# State of California
# Office of Administrative Law

**In re:**
**Bureau of Cannabis Control**

**Regulatory Action:**

**Title 16, California Code of Regulations**

**Adopt sections:** 5000, 5001, 5002, 5003, 5004, 5005, 5006, 5007, 5008, 5009, 5010, 5011, 5012, 5013, 5014, 5015, 5016, 5017, 5018, 5019, 5020, 5021, 5022, 5023, 5024, 5025, 5026, 5027, 5028, 5029, 5030, 5031, 5032, 5033, 5034, 5035, 5036, 5037, 5038, 5039, 5040, 5041, 5042, 5043, 5044, 5045, 5046, 5047, 5048, 5049, 5050, 5051, 5052, 5053, 5054, 5055, 5300, 5301, 5302, 5303, 5304, 5305, 5306, 5307, 5308, 5309, 5310, 5311, 5312, 5313, 5314, 5315, 5400, 5401, 5402, 5403, 5404, 5405, 5406, 5407, 5408, 5409, 5410, 5411, 5412, 5413, 5414, 5415, 5416, 5417, 5418, 5419, 5420, 5421, 5422, 5423, 5424, 5425, 5426, 5500, 5501, 5502, 5503, 5504, 5505, 5506, 5600, 5601, 5602, 5603, 5700, 5701, 5702, 5703, 5704, 5705, 5706, 5707, 5708, 5709, 5710, 5711, 5712, 5713, 5714, 5715, 5716, 5717, 5718, 5719, 5720, 5721, 5722, 5723, 5724, 5725, 5726, 5727, 5728, 5729, 5730, 5731, 5732, 5733, 5734, 5735, 5736, 5737, 5738, 5739, 5800, 5801, 5802, 5803, 5804, 5805, 5806, 5807, 5808, 5809, 5810, 5811, 5812, 5813, 5814

**NOTICE OF APPROVAL OF EMERGENCY REGULATORY ACTION**

**Government Code Sections 11346.1 and 11349.6**

**OAL Matter Number: 2017-1127-05**

**OAL Matter Type: Emergency (E)**

In this emergency rulemaking action, the Bureau of Cannabis Control proposes to adopt regulations in the California Code of Regulations to implement, interpret, and make specific the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), found in Business & Professions Code, section 26000 et seq. These regulations provide licensing and enforcement criteria for commercial cannabis businesses in California, including distributors, retailers, microbusinesses, temporary cannabis events, and testing laboratories. These regulations inform applicants for licensure of the applicable meaning of key statutory terms, identify the documents and supplemental information required in an application, and provide specific clarification of terms, prohibitions, and conditions for compliance with MAUCRSA. This is a deemed emergency action pursuant to section 26013, subdivision (b)(3), of the Business & Professions Code.

OAL approves this emergency regulatory action pursuant to sections 11346.1 and 11349.6 of the Government Code.

This emergency regulatory action is effective on 12/7/2017 and will expire on 6/6/2018. The Certificate of Compliance for this action is due no later than 6/5/2018.

Date: December 7, 2017

Erid Partington
Senior Attorney

For: Debra M. Cornez
Director

Original: Lori Ajax, Bureau Chief

Copy: Tamara Colson
C.J. Croyts-Schooley

STATE OF CALIFORNIA--OFFICE OF ADMINISTRATIVE LAW

# NOTICE PUBLICATION/REGULATIONS SUBMISSION

EMERGENCY

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

| OAL FILE NUMBERS | NOTICE FILE NUMBER | REGULATORY ACTION NUMBER | EMERGENCY NUMBER |
|---|---|---|---|
| | Z- | | 2017-1127-05E |

ENDORSED - FILED
in the office of the Secretary of State
of the State of California
DEC 07 2017
3:45 P.M.

For use by Office of Administrative Law (OAL) only

2017 NOV 27 P 5:00

OFFICE OF ADMINISTRATIVE LAW

NOTICE | REGULATIONS

**AGENCY WITH RULEMAKING AUTHORITY**
Department of Consumer Affairs - Bureau of Cannabis Control

AGENCY FILE NUMBER (If any)

## A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

| 1. SUBJECT OF NOTICE | TITLE(S) | FIRST SECTION AFFECTED | 2. REQUESTED PUBLICATION DATE |
|---|---|---|---|
| | | | |

| 3. NOTICE TYPE | 4. AGENCY CONTACT PERSON | TELEPHONE NUMBER | FAX NUMBER (Optional) |
|---|---|---|---|
| ☐ Notice re Proposed Regulatory Action ☐ Other | | | |

| OAL USE ONLY | ACTION ON PROPOSED NOTICE | NOTICE REGISTER NUMBER | PUBLICATION DATE |
|---|---|---|---|
| | ☐ Approved as Submitted ☐ Approved as Modified ☐ Disapproved/ Withdrawn | | |

## B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

| 1a. SUBJECT OF REGULATION(S) | 1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S) |
|---|---|
| Commercial Cannabis Regulation | |

2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) **(Including title 26, if toxics related)**

| SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.) | |
|---|---|
| | ADOPT: See attached |
| | AMEND: |
| TITLE(S): 16 | REPEAL: |

3. TYPE OF FILING

- ☐ Regular Rulemaking (Gov. Code §11346)
- ☐ Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)
- ☒ Emergency (Gov. Code, §11346.1(b))
- ☐ Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.
- ☐ Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)
- ☐ Emergency Readopt (Gov. Code, §11346.1(h))
- ☐ File & Print
- ☒ Other (Specify) pursuant to BPC 26013
- ☐ Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
- ☐ Print Only

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)
per agency request

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

- ☐ Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))
- ☒ Effective on filing with Secretary of State
- ☐ §100 Changes Without Regulatory Effect
- ☐ Effective other (Specify)

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

- ☐ Department of Finance (Form STD. 399) (SAM §6660)
- ☐ Fair Political Practices Commission
- ☐ State Fire Marshal
- ☒ Other (Specify) Dean R. Grafilo, Director, Department of Consumer Affairs — Dean R Grafilo 11/21/17

| 7. CONTACT PERSON | TELEPHONE NUMBER | FAX NUMBER (Optional) | E-MAIL ADDRESS (Optional) |
|---|---|---|---|
| CJ Croyts-Schooley | (916) 574-8102 | (916) 574-8676 | C.J.Croyts-Schooley@dca.ca.gov |

8. **I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.**

SIGNATURE OF AGENCY HEAD OR DESIGNEE — DATE: 11/20/17

TYPED NAME AND TITLE OF SIGNATORY
Lori Ajax, Bureau Chief, Bureau of Cannabis Control

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

DEC 07 2017

Office of Administrative Law

**SECTION(S) AFFECTED:**

**Adopt**

Cal. Code Regs., Tit. 16, §§ 5000, 5001, 5002, 5003, 5004, 5005, 5006, 5007, 5008, 5009, 5010, 5011, 5012, 5013, 5014, 5015, 5016, 5017, 5018, 5019, 5020, 5021, 5022, 5023, 5024, 5025, 5026, 5027, 5028, 5029, 5030, 5031, 5032, 5033, 5034, 5035, 5036, 5037, 5038, 5039, 5040, 5041, 5042, 5043, 5044, 5045, 5046, 5047, 5048, 5049, 5050, 5051, 5052, 5053, 5054, 5055, 5300, 5301, 5302, 5303, 5304, 5305, 5306, 5307, 5308, 5309, 5310, 5311, 5312, 5313, 5314, 5315, 5400, 5401, 5402, 5403, 5404, 5405, 5406, 5407, 5408, 5409, 5410, 5411, 5412, 5413, 5414, 5415, 5416, 5417, 5418, 5419, 5420, 5421, 5422, 5423, 5424, 5425, 5426, 5500, 5501, 5502, 5503, 5504, 5505, 5506, 5600, 5601, 5602, 5603, 5700, 5701, 5702, 5703, 5704, 5705, 5706, 5707, 5708, 5709, 5710, 5711, 5712, 5713, 5714, 5715, 5716, 5717, 5718, 5719, 5720, 5721, 5722, 5723, 5724, 5725, 5726, 5727, 5728, 5729, 5730, 5731, 5732, 5733, 5734, 5735, 5736, 5737, 5738, 5739, 5800, 5801, 5802, 5803, 5804, 5805, 5806, 5807, 5808, 5809, 5810, 5811, 5812, 5813, and 5814

# BUREAU OF CANNABIS CONTROL
# PROPOSED TEXT OF REGULATIONS

***The following is new text to be added to the California Code of Regulations***

## CALIFORNIA CODE OF REGULATIONS
## TITLE 16
## DIVISION 42. BUREAU OF CANNABIS CONTROL

### Chapter 1. ALL BUREAU LICENSEES

### Article 1. Division Definitions

### § 5000. Definitions

For the purposes of this division, the definitions in this section shall govern the construction of this division unless otherwise indicated.

(a) "Act" means the Medicinal and Adult-Use Cannabis Regulation and Safety Act.

(b) "Bureau" means the Bureau of Cannabis Control, previously named the Bureau of Marijuana Control, Bureau of Medical Cannabis Regulation, and Bureau of Medical Marijuana Regulation.

(c) "Cannabis goods" means cannabis, including dried flower, and products containing cannabis.

(d) "Cannabis waste" means waste that is not hazardous waste, as defined in Public Resources Code section 40141, that contains cannabis and that has been made unusable and unrecognizable in the manner prescribed in sections 5054 and 5055 of this division.

(e) "Canopy" means the designated area(s) at a licensed premise that will contain mature plants at any point in time.

(f) "Delivery employee" means an individual employed by a retailer who delivers cannabis goods from the retailer premises to a customer at a physical address.

(g) "Free cannabis goods" means any amount of cannabis goods provided to any person without cost or payment or exchange of any other thing of value.

(h) "Limited-access area" means an area in which cannabis goods are stored or held and is only accessible to a licensee and its employees and contractors.

(i) "Lot number" or "batch number" means a distinctive group of numbers, letters, or symbols or any combination of these that is unique to a group of cannabis goods.

(j) "Medicinal cannabis patient" includes a qualified patient as defined in Health and Safety Code section 11362.7 and a person in possession of a valid identification card issued under Health and Safety Code section 11362.71.

(k) "Nonvolatile solvent" means any solvent used in the extraction process that is not a volatile solvent. For purposes of this division, a nonvolatile solvent includes carbon dioxide ($CO_2$) used for extraction and ethanol used for extraction or post-extraction processing.

(l) "Package" and "Packaging" means any container or wrapper that may be used for enclosing or containing any cannabis goods for final retail sale. "Package" and "packaging" does not include a shipping container or outer wrapping used solely for the transport of cannabis goods in bulk quantity to a licensee.

(m) "Publicly owned land" means any building or real property that is owned by a city, county, state, federal, or other government entity.

(n) "Residential area" is an area that is within 600 feet of any single-family or multifamily residence, other than commercial hotels, motels, and similar establishments for temporary lodging.

(o) "Retail area" means a building, room, or other area that is open to the public, upon the retailer premises in which cannabis goods are sold or displayed.

(p) "Security monitoring" means the continuous and uninterrupted attention to potential alarm signals that can be transmitted from a security alarm system for the purpose of summoning law enforcement.

(q) "Sublet" means to lease or rent all or part of a leased or rented property.

(r) "Transport" means the physical movement of cannabis goods from one licensed premises to another licensed premises.

(s) "Vehicle alarm system" is a device or series of devices installed to discourage theft of the vehicle or its contents and is intended to summon general attention or to summon law enforcement as a result of an indication of an attempted breach of the vehicle.

Authority: Section 26013, Business and Professions Code. Reference: Section 26013, Business and Professions Code.

**Article 2. Applications**

**§ 5001. Temporary License Application Requirements**

(a) Temporary license applications may be completed and submitted online at www.bcc.ca.gov or completed in hard copy and submitted by delivering a printed copy to the Bureau's office(s).

(b) Applicants who submit their applications online shall first register for a user account. To register for a user account, the applicant shall do all of the following:

(1) Create a user name, password, and security question and answer;

(2) Provide an email address; and

(3) Provide the owner's first and last name, primary phone number, social security number or individual taxpayer identification number, date of birth, and mailing address.

(c) An application must be completed by an owner as defined by section 5003 of this division. An application must be submitted to the Bureau for each temporary license applied for. An application for a temporary license includes:

(1) The legal business name of the applicant.

(2) The email address of the applicant's business and the telephone number for the premises.

(3) The business' federal employer identification number.

(4) A description of the business organizational structure of the applicant, such as partnership or corporation.

(5) The temporary license type that is being requested.

(6) The license designation requested, A-license or M-license, for all license types other than testing laboratories.

(7) The contact information for the applicant's designated primary contact person including the name, title, phone number, and email address of the individual.

(8) For each owner who meets the criteria of Business and Professions Code section 26001(al), the owner's name, title, percentage of ownership, mailing address, telephone number, and email address if applicable.

(9) The physical address of the premises to be licensed.

(10) Evidence that the applicant has the legal right to occupy and use the proposed location that complies with section 5007 of this division.

(11) A premises diagram pursuant to section 5006.

(12) A copy of a valid license, permit, or other authorization issued by a local jurisdiction, that enables the applicant to conduct commercial cannabis activity at the location requested for the temporary license. For purposes of this section, "other authorization" shall include, at a minimum, a written statement or reference that clearly indicates the local jurisdiction intended to grant permission for the commercial cannabis activity or to the person to conduct commercial cannabis activity at the premises. Upon receipt of the application, the Bureau shall contact the applicable local jurisdiction to confirm the validity of the authorization. If the local jurisdiction does not respond within 10 calendar days, the Bureau shall consider the authorization valid.

(13) Attestation to the following statement: Under penalty of perjury, I hereby declare that the information contained within and submitted with the application is complete, true, and accurate. I understand that a misrepresentation of fact is cause for rejection of this application, denial of the license, or revocation of a license issued.

(d) A temporary license is a conditional license that authorizes the licensee to engage in commercial cannabis activity as would be permitted under the privileges of a non-temporary license of the same type. A temporary licensee shall follow all applicable rules and regulations as would be required if the licensee held a non-temporary license of the same type.

(e) A temporary license does not obligate the Bureau to issue a non-temporary license nor does the temporary license create a vested right in the holder to either an extension of the temporary license or to the granting of a subsequent non-temporary license.

(f) A temporary license issued under this section shall be valid for 120 days from the effective date. No temporary license shall be effective prior to January 1, 2018.

(g) A temporary license may be extended by the Bureau for additional 90-day periods if a complete application for an annual license has been submitted to the Bureau pursuant to section 5002 of this division prior to the initial expiration date of the temporary license.

Authority: Section 26013, Business and Professions Code. Reference: Section 26050.1, Business and Professions Code.

**§ 5002. Annual License Application Requirements**

(a) Applications may be completed and submitted online at www.bcc.ca.gov or completed in hard copy and submitted by delivering a printed copy to the Bureau's office(s).

(b) Applicants who submit their applications online shall first register for a user account. To register for a user account, the applicant shall do all of the following:

(1) Create a user name, password, and security question and answer;

(2) Provide an email address; and

(3) Provide the owner's first and last name, primary phone number, social security number or individual taxpayer identification number, date of birth, and mailing address.

(c) An application must be completed by an owner as defined by section 5003 of this division. An application must be submitted to the Bureau for each cannabis license applied for. An application for an annual cannabis license includes the following:

(1) The name of the applicant. For applicants who are individuals, the applicant shall provide both the first and last name of the individual. For applicants who are business entities, the applicant shall provide the legal business name of the applicant.

(2) If applicable, the business trade name ("DBA") of the applicant.

(3) The license type the applicant is applying for, including A-license or M-license designation for all license types other than testing laboratories.

(4) Payment of an application fee pursuant to section 5014 of this division.

(5) Whether the owner is serving or has previously served in the military. Disclosure of military service is voluntary. An applicant who has served as an active duty member of the Armed Forces of the United States and was honorably discharged and who can provide evidence of such honorable discharge shall have his or her application expedited pursuant to Business and Professions Code section 115.4.

(6) A list of the license types and the license numbers issued from the Bureau and all other state cannabis licensing authorities that the applicant holds, including the date the license was issued and the licensing authority that issued the license.

(7) Whether the applicant has been denied a license or has had a license suspended or revoked by the Bureau or any other state cannabis licensing authority. The applicant shall provide the type of license applied for, the name of the licensing authority that denied the application, and the date of denial.

(8) The physical address of the premises.

(9) The mailing address for the applicant, if different from the premises address.

(10) The telephone number for the premises.

(11) The website address and email address of the applicant's business.

(12) The business' federal employer identification number.

(13) Contact information for the applicant's designated primary contact person including the name, title, phone number, and email address of the individual.

(14) A description of the business organizational structure of the applicant, such as partnership or corporation.

(15) The business-formation documents, which may include, but are not limited to, articles of incorporation, operating agreements, partnership agreements, and fictitious business name statements. The applicant shall also provide all documents filed with the California Secretary of State, which may include, but are not limited to, articles of incorporation, certificates of stock, articles of organization, certificates of limited partnership, and statements of partnership authority.

(16) A list of every fictitious business name the applicant is operating under including the address where the business is located.

(17) A commercial cannabis business that is a foreign corporation shall include in its application the certificate of qualification issued by the Secretary of State of California.

(18) The applicant shall supply the following financial information:

(A) A list of funds belonging to the applicant held in savings, checking, or other accounts maintained by a financial institution. The applicant shall provide, for each account, the financial institution's name, the financial institution's address, account type, account number, and the amount of money in the account.

(B) A list of loans made to the applicant. For each loan, the applicant shall provide the amount of the loan, the date of the loan, term(s) of the loan, security provided for the loan, and the name, address, and phone number of the lender.

(C) A list of investments made into the applicant's commercial cannabis business. For each investment, the applicant shall provide the amount of the investment, the date of the investment, term(s) of the investment, and the name, address, and phone number of the investor.

(D) A list of all gifts of any kind given to the applicant for its use in conducting commercial cannabis activity. For each gift, the applicant shall provide the value of the gift or description of the gift, and the name, address, and phone number of the provider of the gift.

(19) A complete list of every individual who has a financial interest in the commercial cannabis business as defined in section 5004 of this division, who is not an owner as defined in Business and Professions Code section 26001(al).

(20) A complete list of every owner of the applicant as defined in Business and Professions Code section 26001(al). Each individual named on this list shall submit the following information:

(A) The full name of the owner.

(B) The owner's title within the applicant entity.

(C) The owner's date of birth and place of birth.

(D) The owner's social security number or individual taxpayer identification number.

(E) The owner's mailing address.

(F) The owner's telephone number. This may include a number for the owner's home, business, or mobile telephone.

(G) The owner's email address.

(H) The owner's current employer.

(I) The percentage of the ownership interest held in the applicant entity by the owner.

(J) Whether the owner has an ownership or a financial interest as defined in sections 5003 and 5004, respectively, of this division in any other commercial cannabis business licensed under the Act.

(K) A copy of the owner's government-issued identification. Acceptable forms of identification are a document issued by a federal, state, county, or municipal government that includes the name, date of birth, physical description, and picture of the person, such as a driver license.

(L) A detailed description of the owner's convictions. A conviction within the meaning of this section means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Convictions dismissed under Penal Code section 1203.4 or equivalent non-California law must be disclosed. Convictions dismissed under Health and Safety Code section 11361.8 or equivalent non-California law must be disclosed. Juvenile adjudications and traffic infractions under $300 that did not involve alcohol, dangerous drugs, or controlled substances do not need to be included. For each conviction, the owner shall provide the following:

(i) The date of conviction.

(ii) Dates of incarceration, if applicable.

(iii) Dates of probation, if applicable.

(iv) Dates of parole, if applicable.

(v) A detailed description of the offense for which the owner was convicted.

(vi) A statement of rehabilitation for each conviction. The statement of rehabilitation is to be written by the owner and may contain evidence that the owner would like the Bureau to consider that demonstrates the owner's fitness for licensure. Supporting evidence may be attached to the statement of rehabilitation and may include, but is not limited to, a certificate of rehabilitation under Penal Code section 4852.01, and dated letters of reference from employers, instructors, or professional counselors that contain valid contact information for the individual providing the reference.

(M) If applicable, a detailed description of any suspension of a commercial cannabis license, revocation of a commercial cannabis license, or sanctions for unlicensed commercial cannabis activity by a licensing authority or local agency against the applicant or a business entity in which the applicant was an owner or officer within the three years immediately preceding the date of the application.

(N) Attestation to the following statement: Under penalty of perjury, I hereby declare that the information contained within and submitted with the application is complete, true, and accurate. I understand that a misrepresentation of fact is cause for rejection of this application, denial of the license, or revocation of a license issued.

(21) Evidence that the applicant has the legal right to occupy and use the proposed location that complies with section 5007 of this division.

(22) Evidence that the proposed premises is in compliance with Business and Professions Code section 26054(b).

(23) For an applicant with 20 or more employees, the applicant shall attest that the applicant has entered into a labor peace agreement and will abide by the terms of the agreement, and the applicant shall provide a copy of the agreement to the Bureau. For applicants who have not yet

entered into a labor peace agreement, the applicant shall provide a notarized statement indicating that the applicant will enter into and abide by the terms of a labor peace agreement.

(24) The applicant shall provide a valid seller's permit number issued by the California Department of Tax and Fee Administration, if applicable. If the applicant has not yet received a seller's permit, the applicant shall attest that the applicant is currently applying for a seller's permit.

(25) A diagram of the premises as required by section 5006 of this division.

(26) Proof of a bond as required by section 5008 of this division.

(27) For testing laboratory applications, the certificate(s) of accreditation as required by section 5702 of this division, or the information required for a provisional license as required by section 5703 of this division.

(28) When an applicant provides a license, permit, or other authorization from the local jurisdiction where the licensed premises will be or is located, the Bureau will notify the applicable local jurisdiction to confirm the validity of the authorization. If the local jurisdiction does not respond within 10 calendar days, the Bureau shall consider the authorization valid.

(29) All licensee applications shall include a detailed description of the applicant's operating procedures including the following (if applicable):

(A) Transportation Procedures

(i) A description of the applicant's procedure for transportation of cannabis goods, including whether or not the applicant will be transporting cannabis goods or contracting for transportation services.

(B) Inventory Procedures

(i) A description of the applicant's procedure for receiving shipments of inventory.

(ii) Where the applicant's inventory will be stored on the premises and how records of the inventory will be maintained.

(iii) The applicant's procedure for performing inventory reconciliation and for ensuring that inventory records are accurate.

(C) Non-Laboratory Quality Control Procedures

(i) The applicant's procedures for preventing the deterioration of cannabis goods held by the applicant.

(ii) The applicant's procedures for ensuring that cannabis goods are properly packaged and labeled prior to retail sale.

(iii) The applicant's procedures for ensuring that a licensed testing laboratory samples and analyzes cannabis goods held by the applicant.

(D) Security Procedures

(i) The applicant's procedure for allowing individuals access to the premises.

(ii) A description of the applicant's video surveillance system including camera placement and procedures for the maintenance of video surveillance equipment.

(iii) How the applicant will ensure that all access points to the premises will be secured, including the use of security personnel.

(iv) A description of the applicant's security alarm system.

(30) For applicants applying for a microbusiness license, the application shall include a detailed description of the applicant's operating procedures required by this section for each cannabis activity the applicant intends to engage in.

(31) For applicants applying for a testing laboratory license, in addition to the operating procedures required under subsection (c)(29) of this section, the standard application shall include the operating procedures required by chapter 6 of this division.

(32) The limited waiver of sovereign immunity required by section 5009 of this division, if applicable.

(33) Evidence of exemption from, or compliance with, the California Environmental Quality Act as required by section 5010.

Authority: Sections 115.4 and 26013, Business and Professions Code. Reference: Sections 115.4, 144 and 26051.5, Business and Professions Code.

**§ 5003. Designation of Owner**

(a) All applicants for a commercial cannabis license shall have at a minimum one individual who meets the definition of "owner" under Business and Professions Code section 26001(al) and who will submit the information required of owners under section 5002.

(b) "Owner" means any of the following:

(1) A person with an aggregate ownership interest of 20 percent or more in the person applying for a license or a licensee, unless the interest is solely a security, lien, or encumbrance.

(2) The chief executive officer of a nonprofit or other entity.

(3) A member of the board of directors of a nonprofit.

(4) An individual who will be participating in the direction, control, or management of the person applying for a license. An owner who is an individual participating in the direction, control, or management of the commercial cannabis business includes any of the following:

(A) A general partner of a commercial cannabis business that is organized as a partnership.

(B) A non-member manager or managing member of a limited liability company of a commercial cannabis business that is organized as a limited liability company.

(C) An officer or director of a commercial cannabis business that is organized as a corporation.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26001, 26012 and 26013, Business and Professions Code.

**§ 5004. Financial Interest in a Commercial Cannabis Business**

(a) A financial interest means an investment into a commercial cannabis business, a loan provided to a commercial cannabis business, or any other equity interest in a commercial cannabis business except as provided in subsection (c).

(b) The license application shall include the name, birthdate, and government-issued identification type and number for all individuals who have a financial interest in a commercial cannabis business but are not owners as defined in Business and Professions Code section 26001(al). These individuals shall not be required to submit the information required of owners under section 5002(c)(20).

(c) Notwithstanding subsection (b), the following persons are not required to be listed on an application for licensure under section 5002(c)(19):

(1) A bank or financial institution whose interest constitutes a loan;

(2) Persons whose only financial interest in the commercial cannabis business is through an interest in a diversified mutual fund, blind trust, or similar instrument;

(3) Persons whose only financial interest is a security interest, lien, or encumbrance on property that will be used by the commercial cannabis business; and

(4) Persons who hold a share of stock that is less than 5 percent of the total shares in a publicly traded company.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26012 and 26051.5, Business and Professions Code.

**§ 5005. Personnel Prohibited from Holding Licenses**

(a) A license authorized by the Act and issued by the Bureau may not be held by, or issued to, any person holding office in, or employed by, any agency of the State of California or any of its political subdivisions when the duties of such person have to do with the enforcement of the Act or any other penal provisions of law of this State prohibiting or regulating the sale, use, possession, transportation, distribution, testing, manufacturing, or cultivation of cannabis goods.

(b) This section applies to, but is not limited to, any person employed in the State of California Department of Justice as a peace officer, in any district attorney's office, in any city attorney's office, in any sheriff's office, or in any local police department.

(c) No person listed in subsection (a) or (b) may have any ownership interest, directly or indirectly, in any business to be operated or conducted under a cannabis license.

(d) This section does not apply to any person who holds a license in the capacity of executor, administrator, or guardian.

Authority: Section 26013, Business and Professions Code. Reference: Section 26012, Business and Professions Code.

**§ 5006. Premises Diagram**

(a) An applicant shall submit to the Bureau, with the application, a complete and detailed diagram of the proposed premises.

(b) The diagram shall show the boundaries of the property and the proposed premises to be licensed, showing all boundaries, dimensions, entrances and exits, interior partitions, walls, rooms, windows, doorways, and common or shared entryways, and shall include a brief statement or description of the principal activity to be conducted therein.

(c) The diagram shall show and identify commercial cannabis activities that will take place in each area of the premises, and identify limited-access areas.

(d) The diagram shall show where all cameras are located and assign a number to each camera for identification purposes.

(e) The diagram shall be to scale.

(f) The diagram shall not contain any highlighting and the markings on the diagram shall be in black-and-white print.

(g) If the proposed premises consists of only a portion of a property, the diagram must be labeled indicating which part of the property is the proposed premises and what the remaining property is used for.

(h) If the proposed premises will be a microbusiness that includes cultivation activities, in addition to the requirements of subsections (b) through (g), the premises diagram shall also include all the required information for a premises diagram under section 5501(d) of this division.

Authority: Section 26013, Business and Professions Code. Reference: Section 26051.5, Business and Professions Code.

**§ 5007. Landowner Approval**

(a) If the applicant is not the landowner of the real property upon which the premises is located, the applicant shall provide to the Bureau a document from the landowner or the landowner's agent that states that the applicant has the right to occupy the property and acknowledges that the applicant may use the property for the commercial cannabis activity for which the applicant is applying for licensure. An applicant shall also provide a copy of the rental agreement, as applicable.

(b) If the applicant is the landowner of the real property upon which the premises is located, the applicant shall provide to the Bureau a copy of the title or deed to the property.

Authority: Section 26013, Business and Professions Code. Reference: Section 26051.5, Business and Professions Code.

**§ 5008. Bond**

An applicant shall provide proof of having obtained a surety bond of at least $5,000 payable to the State of California to ensure payment of the cost incurred for the destruction of cannabis goods necessitated by a violation of the Act or the regulations adopted thereunder. All bonds required under this regulation must be issued by a corporate surety licensed to transact surety business in the State of California.

Authority: Section 26013, Business and Professions Code. Reference: Section 26051.5, Business and Professions Code.

**§ 5009. Limited Waiver of Sovereign Immunity**

(a) Any applicant or licensee that may fall within the scope of sovereign immunity that may be asserted by a federally recognized tribe or other sovereign entity must waive any sovereign immunity defense that the applicant or licensee may have, may be asserted on its behalf, or may otherwise be asserted in any state administrative or judicial enforcement actions against the applicant or licensee, regardless of the form of relief sought, whether monetary or otherwise, under the state laws and regulations governing commercial cannabis activity. The applicant or licensee must submit a written waiver of sovereign immunity to the Bureau with any license application or renewal, which is valid for the period of the license. The written waiver shall include that the applicant or licensee has the lawful authority to enter into the waiver required by this section, the applicant or licensee hereby waives sovereign immunity, and the applicant or licensee agrees to do all of the following:

(1) Provide documentation to the Bureau that establishes that the applicant or licensee has the lawful authority to enter into the waiver required by this section;

(2) Conduct all commercial cannabis activity in full compliance with the state laws and regulations governing commercial cannabis activity, including submission to all enforcement provisions thereof;

(3) Allow access as required by state statute or regulation by persons or entities charged with duties under the state laws and regulations governing commercial cannabis activity to any premises or property at which the applicant conducts any commercial cannabis activity, including premises or property where records of commercial cannabis activity are maintained by or for the applicant or licensee;

(4) Provide any and all records, reports, and other documents as may be required under the state laws and regulations governing commercial cannabis activity;

(5) Conduct commercial cannabis activity with other state commercial cannabis licensees only, unless otherwise specified by state law;

(6) Meet all of the requirements for licensure under the state laws and regulations governing the conduct of commercial cannabis activity, and provide truthful and accurate documentation and other information of the applicant's qualifications and suitability for licensure as may be requested; and

(7) Submit to the personal and subject matter jurisdiction of the California courts to address any matter related to the waiver or the commercial cannabis application, license, or activity, and that all such matters and proceedings shall be governed, construed and enforced in accordance with California substantive and procedural law, including but not limited to the Medicinal and Adult-Use Regulation and Safety Act and the Administrative Procedure Act.

(b) The Bureau shall not approve an application for a state license if approval of the license would violate the provisions of any local ordinance or regulation adopted in accordance with Business and Professions Code section 26200 that is issued by the county or, if within a city, the city, within which the licensed premises is to be located.

(c) Any applicant or licensee must immediately notify the Bureau of any changes that may materially affect the applicant or licensee's compliance with subsection (a) of this section.

(d) Any failure by an applicant or licensee to comply with the requirements of subsections (b) or (c) shall be a basis for denial of an application or renewal or discipline of a licensee.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26012, 26050 and 26051.5, Business and Professions Code.

**§ 5010. Compliance with the California Environmental Quality Act**

(a) All applicants shall provide evidence of exemption from, or compliance with, Division 13 of the Public Resources Code, California Environmental Quality Act (CEQA), as required by section 5002(c)(33) of this division.

(b) The evidence provided pursuant to subsection (a) of this section shall be one of the following:

(1) A copy of the applicant's license, permit, or other authorization from the local jurisdiction if the local jurisdiction has adopted an ordinance, rule, or regulation pursuant to Business and Professions Code section 26055(h) that requires discretionary review and approval of permits, licenses, or other authorizations to engage in commercial cannabis activity.

(2) A copy of the Notice of Determination or Notice of Exemption and a copy of the CEQA document, or reference to where it can be located electronically, if the applicant does not wish to provide a copy of the license, permit, or other authorization provided by the local jurisdiction or if the local jurisdiction has not adopted an ordinance, rule, or regulation pursuant to Business and Professions Code section 26055(h) that requires discretionary review and approval of permits, licenses, or other authorizations to engage in commercial cannabis activity.

(c) If an applicant does not have the evidence specified in subsection (b) of this section, or if the local jurisdiction did not prepare a CEQA document, the applicant will be responsible for the preparation of an environmental document in compliance with CEQA that can be approved or certified by the Bureau, unless the Bureau specifies otherwise.

Authority: Section 26013, Business and Professions Code. Reference: Section 26055, Business and Professions Code.

**§ 5011. Additional Information**

The Bureau may request additional information and documents from the applicant. The Bureau will provide the applicant a deadline for submittal of additional information. The Bureau will consider the complexity of the information requested and the ease with which the information can be obtained and transmitted to the Bureau by the applicant in determining the deadline.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26031, 26050 and 26051.5, Business and Professions Code.

**§ 5012. Incomplete Applications**

(a) If the Bureau determines that the application is incomplete, the Bureau may provide notice to the applicant in accordance with Business and Professions Code section 124.

(b) If the Bureau issues a notice pursuant to Business and Professions Code section 124, an applicant has one year from the date of the notice in subsection (a) to correct all deficiencies. If the applicant fails to correct the deficiencies within the one-year period and has not responded to the Bureau's attempts to contact the applicant, the application shall be considered abandoned under Business and Professions Code section 142.

(c) An applicant may reapply at any time following an abandoned application.

(d) The Bureau will not refund application fees for an incomplete or abandoned application.

Authority: Section 26013, Business and Professions Code. Reference: Sections 124, 142, 26050 and 26051.5, Business and Professions Code.

**§ 5013. Withdrawal of Application**

(a) An applicant may withdraw an application at any time prior to the Bureau's issuance of a license or denial of a license.

(b) Requests to withdraw an application must be submitted to the Bureau in writing, dated, and signed by the applicant.

(c) In accordance with Business and Professions Code section 118, withdrawal of an application shall not, unless the Bureau has consented in writing to such withdrawal, deprive the Bureau of its authority to institute or continue a proceeding against the applicant for the denial of the license upon any ground provided by law or to enter an order denying the license upon any such ground.

(d) The Bureau will not refund application fees for a withdrawn application.

(e) An applicant may reapply at any time following the withdrawal of an application and will be required to submit a new application and fee.

Authority: Section 26013, Business and Professions Code. Reference: Sections 118 and 26050, Business and Professions Code.

**Article 3. Licensing**

**§ 5014. Fees**

(a) The application fee for an annual license under section 5002 of this division, a cannabis event organizer license under section 5600 of this division, a temporary cannabis event license under section 5601 of this division for each event, and physical modification of the premises under section 5027 of this division shall be paid by an applicant or licensee as provided by this division. Applicants and licensees shall pay the appropriate fee as outlined in the following fee schedule.

**Application Fee Schedule**

| License Type | Fee Per Application |
|---|---|
| All Annual Licenses | $ 1,000 |
| Cannabis Event Organizer License | $ 1,000 |
| Temporary Cannabis Event License | $ 1,000 |
| Physical Modification of Premises | $ 500 |

(b) The annual licensing fee for each license shall be paid by an applicant or licensee as provided by this division.

(c) In determining the appropriate license fee to be charged, each applicant or licensee shall estimate the maximum dollar value of its planned operation in terms of the value of the product expected to be tested, distributed, transported, retailed, cultivated and/or manufactured as determined in assessing the 15% excise tax pursuant to Revenue and Taxation Code section 34011. The applicant or licensee will use the maximum dollar value of its planned operation to determine the appropriate fee as outlined in the following fee schedule.

**Annual License Fee Schedule**

| License Type | Operations ($ Max. Per License) | Fee Per License |
|---|---|---|
| Testing Laboratory | up to 50 million | $ 20,000 |
| | greater than 50 million to 500 million | $ 45,000 |
| | greater than 500 million | $ 90,000 |
| Distributor | up to 2 million | $ 1,200 |
| | greater than 2 million to 8 million | $ 5,000 |
| | greater than 8 million to 80 million | $ 36,000 |
| | greater than 80 million | $125,000 |
| Distributor Transport Only Self-Distribution | up to 2 million | $500 |
| | greater than 2 million to 8 million | $2,000 |
| Distributor Transport Only | up to 2 million | $800 |
| | greater than 2 million to 8 million | $2,500 |
| Retailer | up to 0.5 million | $ 4,000 |
| | greater than 0.5 million to 1.5 million | $ 12,000 |
| | greater than 1.5 million to 4.5 million | $ 36,000 |
| | greater than 4.5 million | $ 72,000 |
| Microbusiness | up to 0.5 million | $ 5,000 |
| | greater than 0.5 million to 1.5 million | $ 15,000 |
| | greater than 1.5 million to 4.5 million | $ 42,000 |
| | greater than 4.5 million | $ 120,000 |

(d) Notwithstanding the fees identified above, cannabis event organizers shall pay the appropriate fee as outlined in the following fee schedule.

**Annual License Fee Schedule for Cannabis Event Organizers**

| License Type | Planned Operations (Number of Operations) | Fee Per License |
|---|---|---|
| Event Organizer | 1-10 events annually | $ 5,000 |
| | greater than 10 events annually | $ 10,000 |

(e) No license shall be issued or renewed before the license fee is paid to the Bureau.

(f) All fees are nonrefundable.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26051.5 and 26180, Business and Professions Code.

**§ 5015. Payment of Fees**

(a) Any fee specified in this division shall be made to the Bureau of Cannabis Control by cash, check, money order, debit card, or credit card.

(b) If the fee is paid by debit or credit card:

(1) The payment shall be made through the Bureau's online licensing system; and

(2) The applicant or licensee may be required to pay any associated processing or convenience fees to the third-party vendor processing the payment on behalf of the Bureau.

(c) If the Bureau determines that the licensee paid an amount less than the appropriate licensing fee under section 5014 of this division, the licensee will be required to pay the balance of the appropriate fee and a penalty fee of 50 percent of the appropriate licensing fee. Failure to pay the appropriate fee is grounds for disciplinary action.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26051.5 and 26180, Business and Professions Code

**§ 5016. Priority Licensing**

(a) Priority licensing is available for annual licenses only, and is not applicable to any temporary or cannabis event organizer license.

(b) To be eligible for priority licensing, an applicant must be able to demonstrate that the applicant operated in compliance with the Compassionate Use Act of 1996 and its implementing laws before September 1, 2016. Eligibility for priority licensing shall be established by one of the following methods:

(1) The applicant is included on the list provided to the Bureau by the local jurisdiction in response to the Bureau's request required by Business and Professions Code section 26054.2.

(2) If the local jurisdiction does not provide a list to the Bureau or the applicant's name does not appear on the list provided to the Bureau, the applicant shall provide to the Bureau evidence of operation in compliance with the Compassionate Use Act of 1996. Such evidence shall be in the form of a document issued or signed by the applicant's local jurisdiction that contains the following:

(A) Name of the applicant;

(B) Address of the premises to be licensed;

(C) License type(s) that the applicant is applying to the Bureau for;

(D) Name of the local jurisdiction;

(E) Name of the local jurisdiction office that is responsible for enforcing compliance with the Compassionate Use Act of 1996;

(F) Name and contact information for the person authorized by the local jurisdiction to sign on its behalf;

(G) Signature of the person authorized to sign on behalf of the local jurisdiction; and

(H) A statement to the effect of: "The above–named party is currently conducting commercial cannabis activity in this jurisdiction and has been operating in compliance with the Compassionate Use Act of 1996 since before September 1, 2016."

Authority: Section 26013, Business and Professions Code. Reference: Section 26054.2, Business and Professions Code.

**§ 5017. Substantially Related Offenses and Criteria for Rehabilitation**

(a) For the purpose of license denial, convictions that are substantially related to the qualifications, functions, or duties of the business for which the application is made include:

(1) A violent felony conviction, as specified in subdivision (c) of section 667.5 of the Penal Code.

(2) A serious felony conviction, as specified in subdivision (c) of section 1192.7 of the Penal Code.

(3) A felony conviction involving fraud, deceit, or embezzlement.

(4) A felony conviction for hiring, employing, or using a minor in transporting, carrying, selling, giving away, preparing for sale, or peddling, any controlled substance to a minor; or selling, offering to sell, furnishing, offering to furnish, administering, or giving any controlled substance to a minor.

(5) A felony conviction for drug trafficking with enhancements pursuant to Health and Safety Code section 11370.4 or 11379.8.

(b) Except as provided in subsections (4) and (5) of subsection (a) and notwithstanding Chapter 2 (commencing with Section 480) of Division 1.5 of the Business and Professions Code, a prior conviction, where the sentence, including any term of probation, incarceration, or supervised release, is completed, for possession of, possession for sale, sale, manufacture, transportation, or cultivation of a controlled substance is not considered substantially related, and shall not be the sole ground for denial of a license. Conviction for any controlled substance felony subsequent to licensure shall be grounds for revocation of a license or denial of the renewal of a license.

(c) When evaluating whether an applicant who has been convicted of a criminal offense that is substantially related to the qualifications, functions, or duties of the business for which the application is made should be issued a license, the Bureau shall consider the following criteria of rehabilitation:

(1) The nature and severity of the act or offense;

(2) Whether the person has a felony conviction based on possession or use of cannabis or cannabis products that would not be a felony if the person was convicted of the offense on the date of the person's application;

(3) The applicant's criminal record as a whole;

(4) Evidence of any act committed subsequent to the act or offense under consideration that could be considered grounds for denial, suspension, or revocation of a commercial cannabis activity license;

(5) The time that has elapsed since commission of the act or offense;

(6) The extent to which the applicant has complied with any terms of parole, probation, restitution, or any other sanctions lawfully imposed against the applicant;

(7) If applicable, evidence of dismissal under Penal Code sections 1203.4, 1203.4(a), 1203.41 or another state's similar law;

(8) If applicable, a certificate of rehabilitation obtained under Penal Code section 4852.01 or another state's similar law; and

(9) Other evidence of rehabilitation submitted by the applicant.

(d) If an applicant has been denied a license based on a conviction, the applicant may request a hearing pursuant to Business and Professions Code section 26058 to determine if the applicant should be issued a license.

Authority: Section 26013, Business and Professions Code. Reference: Sections 482 and 26057, Business and Professions Code.

**§ 5018. Additional Grounds for Denial of a License**

In addition to the reasons for denial in Business and Professions Code section 26057, a license may be denied for the following reasons:

(a) The applicant's premises does not fully comply with standards set in regulation.

(b) The applicant's premises is substantially different from the diagram of the premises submitted by the applicant, in that the size, layout, location of common entryways, doorways, or passage ways, means of public entry or exit, or identification of limited-access areas within the licensed premises is not the same.

(c) The applicant denied the Bureau access to the premises.

(d) The applicant made a material misrepresentation on the application.

(e) The applicant did not correct the deficiencies within the application in accordance with sections 5002 and 5012 of this division.

(f) The applicant has been denied a license, permit, or other authorization to engage in commercial cannabis activity by a state or local licensing authority.

(g) The applicant's premises is not in compliance with Division 13 (commencing with Section 21000) of the Public Resources Code.

Authority: Section 26013, Business and Professions Code. Reference: Sections 480, 490, 26012, 26030 and 26050, Business and Professions Code.

**§ 5019. Excessive Concentration**

(a) In determining whether to grant, deny, or renew a license for a retail license or microbusiness license, the Bureau shall consider if an excessive concentration exists in the area where the licensee will operate. For the purposes of this section "excessive concentration" applies when either of the following conditions exist:

(1) The ratio of licensees to population within the census tract or census division in which the applicant premises is located exceeds the ratio of licensees to population in the county in which the applicant premises is located, unless denial of the application would unduly limit the development of the legal market so as to perpetuate the illegal market for cannabis or cannabis products.

(2) The ratio of retail licenses or microbusiness licenses to the population within the census tract, census division, or jurisdiction exceeds that allowable by local ordinance adopted under section 26200.

(b) "Population Within the Census Tract or Census Division" as used in this section means the population as determined by the most recent United States decennial or special census. Such population determination shall not operate to prevent an applicant from establishing that an increase of resident population has occurred within the census tract or census division.

(c) "Population in the County" as used in this section shall be determined by the most recent annual population estimate for California counties published by the Demographic Research Unit, State Department of Finance.

(d) Beginning July 1, 2018, the Bureau shall calculate the ratios described in subsection (a) of this section once every six months using the most current available data. The Bureau's consideration of whether to grant, deny, or renew a license shall be based upon the most recent ratio calculated by the Bureau on the date of the Bureau's decision.

(e) The existence of an excessive concentration shall not be considered in determining whether to grant, deny, or extend a temporary license under Business and Professions Code section 26050.1.

(f) The applicant may provide reliable evidence establishing, to the satisfaction of the Bureau, that a denial of a license would unduly limit the development of the legal market so as to perpetuate the illegal market for cannabis and cannabis products.

Authority: Section 26013, Business and Professions Code. Reference: Section 26051, Business and Professions Code

**§ 5020. Renewal of License**

(a) To timely renew a license, a completed license renewal form and annual license fee pursuant to section 5014 of this division shall be received by the Bureau from the licensee no earlier than 60 calendar days before the expiration of the license and no later than 5:00 p.m. Pacific Time on the last business day before the expiration of the license if the renewal form is submitted to the Bureau at its office(s), or no later than 11:59 p.m. on the last business day before the expiration of the license if the renewal form is submitted to the Bureau through its electronic licensing system. Failure to receive a notice for license renewal does not relieve a licensee of the obligation to renew all licenses as required.

(b) In the event the license is not renewed prior to the expiration date, the licensee must not sell, transfer, transport, manufacture, test, or distribute any commercial cannabis goods until the license is renewed.

(c) A licensee may submit a license renewal form up to 30 days after the license expires. Any late renewal form will be subject to a late fee equal to 50 percent of the applicable licensing fee required by subsection (a).

(d) The license renewal form shall contain the following:

(1) The name of the licensee. For licensees who are individuals, the applicant shall provide both the first and last name of the individual. For licensees who are business entities, the licensee shall provide the legal business name of the applicant.

(2) The license number and expiration date.

(3) The licensee's address of record and premises address.

(4) An attestation that all information provided to the Bureau in the original application under section 5002 of this division or subsequent notification under sections 5023 and 5024 of this division is accurate and current.

(5) A limited waiver of sovereign immunity pursuant to section 5009 of this division.

Authority: Section 26013, Business and Professions Code. Reference: Section 26050, Business and Professions Code.

**§ 5021. Denial of License**

(a) The Bureau may deny an application for a new license or a renewal of a license for any reason specified in section 26057 of the Business and Professions Code, and on any additional grounds including grounds for denial under section 5018 of this division, and grounds for discipline under the Act or this division.

(b) Upon denial of an application for a license or renewal of a license, the Bureau shall notify the applicant in writing of the reasons for denial, and the right to a hearing to contest the denial.

(c) The applicant may request a hearing to contest the denial by submitting a written request to the Bureau.

(1) The written request for a hearing must be postmarked within 30 calendar days of service of the notification of denial.

(2) If the written request for a hearing is not received within the required timeframe, the applicant's right to a hearing is waived.

(3) Upon timely receipt of the written request for hearing, the Bureau shall set a date for hearing to be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

Authority: Section 26013, Business and Professions Code; Reference: Sections 26057 and 26058, Business and Professions Code.

**§ 5022. Surrender and Cancellation of License**

(a) Every licensee who surrenders, abandons, or quits the licensed premises, or who closes the licensed premises for a period exceeding 30 consecutive calendar days, shall, within 10 business days after closing, surrendering, quitting, or abandoning the licensed premises, surrender the license certificate to the Bureau. The Bureau may seize the license certificate of a licensee who fails to comply with the surrender provisions of this section and may proceed to revoke the license or licenses.

(b) A person whose license has been surrendered may submit to the Bureau a written request for the license to be returned. Any request should be submitted to the Bureau prior to the expiration of the surrendered license. The written request shall specify the reason the license was surrendered and why the license should be returned. The Bureau in its discretion may return the license.

(c) The Bureau may cancel the license or licenses of a licensee upon request by the licensee.

Authority: Section 26013, Business and Professions Code. Reference: Section 26050, Business and Professions Code.

**§ 5023. Notification of Changes**

(a) Every licensee shall notify the Bureau in writing within 10 business days of any change to any item listed in the application, with the exception of a change to standard operating procedures. The notification shall be signed by an owner as defined in section 5003 of this division.

(b) If at the time of licensure, a licensee employed less than 20 employees and later employs 20 or more employees, the licensee shall provide to the Bureau a document attesting that the licensee has entered into a labor peace agreement and will abide by the terms of the agreement, and a copy of the agreement, within 30 days of employing 20 or more employees.

(c) Licenses are not transferrable. If one or more of the owners of a license change, a new license application and fee shall be submitted to the Bureau within 10 business days of the effective date of the ownership change. A change in ownership occurs when a new person meets the definition of owner in section 5003 of this division. A change in ownership does not occur when one or more owners leave the business by transferring their ownership interest to the other existing owner(s). In cases where one or more owners leave the business by transferring their ownership interest to the other existing owner(s), the owner or owners that are transferring their interest shall provide a signed statement to the Bureau confirming that they have transferred their interest.

(d) When there is a change in persons with financial interest(s) in the commercial cannabis business that do not meet the requirements for a new license application under this section, the licensee shall submit the information required by sections 5002(c)(19) and 5004 of this division to the Bureau within 10 business days of the change.

(e) In order to change the location of a premises, a licensee shall submit a new application and fee to the Bureau. A licensee shall not begin operating out of a new premises until the Bureau has approved the application.

Authority: Section 26013, Business and Professions Code. Reference: Sections 136 and 26012, Business and Professions Code.

**§ 5024. Death or Incapacity of a Licensee**

(a) In the event of the death, incapacity, receivership, assignment for the benefit of creditors of a licensee, or other event rendering a licensee incapable of performing the duties associated with the license, the licensee's successor in interest (e.g., appointed guardian, executor, administrator, receiver, trustee, or assignee) shall notify the Bureau in writing, within 10 business days.

(b) To continue operations or surrender the existing license, the successor in interest shall submit to the Bureau the following:

(1) The name of the successor in interest.

(2) The name of the licensee for which the successor in interest is succeeding and the license number;

(3) The phone number, mailing address, and email address of the successor in interest; and

(4) Documentation demonstrating that the licensee is incapable of performing the duties associated with the license such as a death certificate or a court order finding the licensee lacks capacity, and documentation demonstrating that the individual making the request is the licensee's successor in interest such as a court order appointing guardianship or will or trust agreement.

(c) The Bureau may give the successor in interest written approval to continue operations on the licensed business premises for a period of time specified by the Bureau:

(1) If the successor in interest or another person has applied for a license from the Bureau for the licensed premises and that application is under review;

(2) If the successor in interest needs additional time to destroy or sell cannabis goods; or

(3) At the discretion of the Bureau.

(d) The licensee's successor in interest is held subject to all terms and conditions under which a state cannabis license is held pursuant to the Act.

(e) The approval creates no vested right to the issuance of a state cannabis license.

Authority: Section 26013, Business and Professions Code. Reference: Section 26012, Business and Professions Code.

**§ 5025. Premises**

(a) Each license shall have a designated premises for the licensee's commercial cannabis activity, which is subject to inspection by the Bureau.

(b) The Bureau may allow a licensee to have the same licensed premises for two separate commercial cannabis licenses if all of the following criteria are met:

(1) The licensee holds both an A-license and an M-license for the identical type of commercial cannabis activity;

(2) The licensee who holds both licenses is identical in name, business formation, and ownership;

(3) The licensee only conducts one type of commercial cannabis activity on the premises;

(4) All cannabis and cannabis products are clearly marked with an "A" or "M"; and

(5) Records are kept separately for each license and clearly indicate that the records are related to the A-license or the M-license.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26001 and 26053, Business and Professions Code.

**§ 5026. Premises Location**

(a) A premises licensed under this division shall not be located within a 600-foot radius of a school providing instruction in kindergarten or any grades 1 through 12, day care center, or youth center that is in existence at the time the license is issued.

(b) Notwithstanding subsection (a), if a local jurisdiction has issued a license or permit to conduct commercial cannabis activity at a premises that is located within a 600-foot radius of a school providing instruction in kindergarten or any grades 1 through 12, day care center, or youth center, the Bureau may approve the premises for licensure if the following conditions are met:

(1) The applicant submits a copy of a valid license or permit from the local jurisdiction with the application for licensure; and

(2) The local jurisdiction notifies the Bureau that the applicant is in compliance with all applicable local ordinances and regulations pursuant to Business and Professions Code section 26055(g)(2)(C).

(c) A premises shall not be in a location that requires persons to pass through a business that sells alcohol or tobacco to access the licensed premises, or that requires persons to pass through the licensed premises to access a business that sells tobacco or alcohol.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26051.5, 26054 and 26055, Business and Professions Code.

**§ 5027. Physical Modification of Premises**

(a) A licensee shall not, without the prior written approval of the Bureau, make a physical change, alteration, or modification of the licensed premises that materially or substantially alters the licensed premises or the use of the licensed premises from the premises diagram originally filed with the license application. A licensee whose premises is to be materially or substantially changed, modified, or altered is responsible for filing a request for premises modification with the Bureau.

(b) Material or substantial changes, alterations, or modifications requiring approval include, but are not limited to, the removal, creation, or relocation of a common entryway, doorway, passage, or a means of public entry or exit, when such common entryway, doorway, or passage alters or changes limited-access areas within the licensed premises.

(c) A licensee shall request approval of a physical change, alteration, or modification in writing, and the request shall include:

(1) A new premises diagram that conforms to requirements in section 5006 of this division; and

(2) A fee pursuant to section 5014 of this division.

(d) A licensee shall provide additional documentation requested by the Bureau to evaluate the licensee's request to modify the premises.

Authority: Section 26013, Business and Professions Code. Reference: Section 26055, Business and Professions Code.

**§ 5028. Subletting of Premises**

A licensee shall not sublet any area designated as the licensed premises for the licensee's commercial cannabis activity.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26013 and 26070, Business and Professions Code

**§ 5029. Transition to Regulated Commercial Cannabis Market**

(a) Beginning January 1, 2018, licensees shall not transport or sell any edible cannabis product that exceeds 10 milligrams of tetrahydrocannabinol (THC) per serving.

(b) Notwithstanding any other regulation in this division, beginning January 1, 2018, and before July 1, 2018, licensees may do all of the following:

(1) Licensees may conduct business with other licensees irrespective of the "M" or "A" designation on their licenses.

(2) Cannabis goods that are not in child-resistant packaging may be sold if they are placed into child-resistant packaging by the retailer at the time of sale.

(3) Non-edible cannabis products that do not meet the THC limits per package specified by the State Department of Public Health in regulation may be transported and sold.

(4) An M-licensee may transport or sell medicinal edible cannabis products that are 10 milligrams of THC or less per serving regardless of the THC amount in the package.

(5) Cannabis goods that do not meet the labeling requirements prescribed by the Act or the State Department of Public Health in regulation may be transported and sold if a sticker with the applicable warning statement under Business and Professions Code section 26120, subdivision (c)(1)(A) or (c)(1)(B), is affixed to the cannabis goods prior to sale by the retailer.

(6) Cannabis goods held in inventory at the time of licensure that have not undergone laboratory testing may be transported and sold if a label stating that the cannabis goods have not been tested as required under Business and Professions Code section 26070(l) is affixed to each package containing the cannabis goods prior to sale by the retailer.

(7) Dried flower held in inventory by a retailer at the time of licensure that is not packaged may be packaged by the retailer into individual packages for sale.

(8) Cannabis products held in inventory by a retailer that do not meet the requirements set by the State Department of Public Health, pursuant to Business and Professions Code sections 26130 and 26131, for ingredients or appearance may be sold by the retailer.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26013 and 26070, Business and Professions Code.

**§ 5030. Licensee's Responsibility for Acts of Employees and Agents**

In construing and enforcing the provisions of the Act and the regulations in this division, the act, omission, or failure of an agent, officer, representative, or other person acting for or employed by a licensee, within the scope of his or her employment or office, shall in every case be deemed the act, omission, or failure of the licensee.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26031 and 26110, Business and Professions Code.

**§ 5031. Employee Age Restriction**

A licensee shall not employ or retain persons under 21 years of age.

Authority: Section 26013, Business and Professions Code. Reference: Section 26140, Business and Professions Code.

**§ 5032. Commercial Cannabis Activity Between Licensees**

(a) All commercial cannabis activity shall be conducted between licensees. Retail licensees may conduct commercial cannabis activity with customers in accordance with chapter 3 of this division.

(b) Beginning July 1, 2018, A-licensees shall only conduct business with A-licensees and M-licensees shall only conduct business with M-licensees, except for testing laboratories.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26001, 26013 and 26053, Business and Professions Code.

**§ 5033. Storage of Inventory**

(a) A licensee shall not store cannabis goods outdoors.

(b) Employee break rooms, changing facilities, and bathrooms shall be separated from all storage areas.

(c) Each location where cannabis goods are stored must be separately licensed.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26012 and 26070, Business and Professions Code.

**§ 5034. Significant Discrepancy in Inventory**

(a) A significant discrepancy in inventory means a difference in actual inventory compared to records pertaining to inventory of at least $5,000 or 2 percent of the average monthly sales of the licensee, whichever is less.

(b) For the purposes of this section, average monthly sales shall be calculated by taking a per month average of the total sales for the previous 6 months. If the licensee has not been in operation for at least 6 months, only the months in which the licensee was operating shall be used in determining average monthly sales.

(c) For the purposes of this section, the licensee's acquisition price shall be used to determine the value of cannabis goods in a licensee's inventory.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5035. Notification of Criminal Acts, Civil Judgments, and Revocation of a Local License, Permit, or Other Authorization After Licensure**

(a) A licensee shall ensure that the Bureau is notified in writing of a criminal conviction of any owner, either by mail or electronic mail, within 48 hours of the conviction. The written notification to the Bureau shall include the date of conviction, the court docket number, the name of the court in which the licensee was convicted, and the specific offense(s) for which the licensee was convicted.

(b) A licensee shall ensure that the Bureau is notified in writing of a civil penalty or judgment rendered against the licensee or any owner in their individual capacity, either by mail or electronic mail, within 48 hours of delivery of the verdict or entry of judgment, whichever is sooner. The written notification shall include the date of verdict or entry of judgment, the court docket number, the name of the court in which the matter was adjudicated, and a description of the civil penalty or judgment rendered against the licensee.

(c) A licensee shall ensure that the Bureau is notified in writing of the revocation of a local license, permit, or other authorization, either by mail or electronic mail within 48 hours of receiving notice of the revocation. The written notification shall include the name of the local agency involved, a written explanation of the proceeding or enforcement action, and the specific violation(s) that led to revocation.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26030 and 26031, Business and Professions Code.

**§ 5036. Notification of Theft, Loss, and Criminal Activity**

(a) A licensee shall notify the Bureau and local law enforcement within 24 hours of discovery of any of the following situations:

(1) The licensee discovers a significant discrepancy, as defined in section 5034 of this division, in its inventory.

(2) The licensee discovers diversion, theft, loss, or any other criminal activity pertaining to the operations of the licensee.

(3) The licensee discovers diversion, theft, loss, or any other criminal activity by an agent or employee of the licensee pertaining to the operations of the licensee.

(4) The licensee discovers loss or unauthorized alteration of records related to cannabis goods, customers, or the licensee's employees or agents.

(5) The licensee discovers any other breach of security.

(b) The notification to the Bureau pursuant to subsection (a) of this section shall be in writing and include the date and time of occurrence of the theft, loss, or criminal activity, the name of the local law enforcement agency that was notified, and a description of the incident including, where applicable, the item(s) that were taken or lost.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5037. Record Retention**

(a) Each licensee shall keep and maintain the following records related to commercial cannabis activity for at least seven years:

(1) Financial records including, but not limited to, bank statements, sales invoices, receipts, tax records, and all records required by the California Department of Tax and Fee Administration (formerly Board of Equalization) under title 18, California Code of Regulations, sections 1698 and 4901.

(2) Personnel records, including each employee's full name, social security or individual tax payer identification number, date employment begins, and date of termination of employment if applicable.

(3) Training records including, but not limited to, the content of the training provided and the names of the employees that received the training.

(4) Contracts with other licensees regarding commercial cannabis activity.

(5) Permits, licenses, and other local authorizations to conduct the licensee's commercial cannabis activity.

(6) Security records, except for surveillance recordings required pursuant to section 5044 of this division.

(7) Records relating to the composting or destruction of cannabis goods.

(8) Documentation for data or information entered into the track and trace system.

(9) All other documents prepared or executed by an owner or his employees or assignees in connection with the licensed commercial cannabis business.

(b) The Bureau may make any examination of the books and records of any licensee as it deems necessary to perform its duties under the Act.

(c) Records shall be kept in a manner that allows the records to be produced for the Bureau at the licensed premises in either hard copy or electronic form, whichever the Bureau requests.

(d) A licensee may contract with a third party to provide custodial or management services of the records. Such a contract shall not relieve the licensee of the licensee's responsibilities under this section.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26160 and 26161, Business and Professions Code.

**§ 5038. Disaster Relief**

(a) If a licensee is unable to comply with any licensing requirements due to a disaster, the licensee may notify the Bureau of this inability to comply and request relief from the specific licensing requirement.

(b) The Bureau may exercise its discretion to provide temporary relief from specific regulatory requirements in this division and from other licensing requirements when allowed by law.

(c) Temporary relief from specific licensing requirements shall be issued for a reasonable amount of time in order to allow the licensee to recover from the disaster.

(d) The Bureau may require that certain conditions be followed in order for a licensee to receive temporary relief from specific licensing requirements.

(e) A licensee shall not be subject to an enforcement action for a violation of a licensing requirement in which the licensee has received temporary relief.

(f) For the purposes of this section, "disaster" means fire, flood, storm, tidal wave, earthquake, or similar public calamity, whether or not resulting from natural causes.

(g) A licensed premises that has been vacated by a licensee due to a disaster shall not be deemed to have been surrendered, abandoned, or quit under section 5022 of this division.

(h) Notwithstanding subsection (a) of this section, if a licensee needs to move cannabis goods stored on the premises to another location immediately to prevent loss, theft, or degradation of the cannabis goods from the disaster, the licensee may move the cannabis goods without obtaining prior approval from the Bureau if the following conditions are met:

(1) The cannabis goods are moved to a secure location where access to the cannabis goods can be restricted to the licensee, its employees, and contractors;

(2) The licensee notifies the Bureau in writing that the cannabis goods have been moved and that the licensee is requesting relief from complying with specific licensing requirements pursuant to subsection (a) of this section within 24 hours of moving the cannabis goods;

(3) The licensee agrees to grant the Bureau access to the location where the cannabis goods have been moved to for inspection; and

(4) The licensee submits in writing to the Bureau within 10 business days of moving the cannabis goods a request for temporary relief that clearly indicates what statutory and regulatory sections relief is requested from, the time period for which the relief is requested, and the reasons relief is needed for the specified amount of time.

Authority: Section 26013, Business and Professions Code. Reference: Section 26012, Business and Professions Code.

## Article 4. Posting and Advertising

### § 5039. License Posting Requirement

Upon issuance of any license, the licensee shall prominently display the license on the licensed premises where it can be viewed by state and local agencies. If the licensed premises is open to the public, the license shall be displayed in an area that is within plain sight of the public.

Authority: Section 26013, Business and Professions Code. Reference: Section 26012, Business and Professions Code.

### § 5040. Advertising Placement

(a) Any advertising or marketing placed in broadcast, cable, radio, print, and digital communications shall only be displayed where at least 71.6 percent of the audience is reasonably expected to be 21 years of age or older, as determined by reliable up-to-date audience composition data.

(b) Upon request, a licensee shall provide to the Bureau audience composition data as required in subsection (a) of this section for advertising or marketing placed by the licensee. This information shall be provided to the Bureau within the time specified by the Bureau.

(c) If the Bureau determines that audience composition data for advertising or marketing provided by a licensee does not comply with the requirements of subsection (a) of this section, or the licensee fails to provide audience composition data to the Bureau within the time specified by the Bureau, the licensee shall remove the advertising or marketing placement in question.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26151 and 26152, Business and Professions Code.

### § 5041. Age Confirmation in Advertising

(a) Prior to any advertising or marketing from the licensee involving direct, individualized communication or dialogue, the licensee shall use age affirmation to verify that the recipient is 21 years of age or older.

(b) For the purposes of this section, direct, individualized communication or dialogue may occur through any form of communication, including in-person, telephone, physical mail, or electronic.

(c) A method of age verification is not necessary for a communication if the licensee can verify that the licensee has previously had the intended recipient undergo a method of age affirmation and the licensee is reasonably certain that the communication will only be received by the intended recipient.

(d) A licensee shall use a method of age affirmation before having a potential customer added to a mailing list, subscribe, or otherwise consent to receiving direct, individualized communication or dialogue controlled by a licensee.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26151 and 26152, Business and Professions Code.

## Article 5. Security

### § 5042. Access to Limited-Access Areas

Licensees shall ensure that any person on the licensed premises, except for employees and contractors of the licensee, are escorted at all times by the licensee or at least one employee of the licensee when in the limited-access areas of the premises.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

### § 5043. Licensee Employee Badge Requirement

All agents, officers, or other persons acting for or employed by a licensee shall display a laminated or plastic-coated identification badge issued by the licensee at all times while engaging in commercial cannabis activity. The identification badge shall, at a minimum, include the licensee's "doing business as" name and license number, the employee's first name, an employee number exclusively assigned to that employee for identification purposes, and a color photograph of the employee that clearly shows the full front of the employee's face and that is at least 1 inch in width and 1.5 inches in height.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

### § 5044. Video Surveillance System

(a) Each licensed premises shall have a digital video surveillance system with a minimum camera resolution of 1280 × 720 pixels.

(b) The surveillance-system storage device or the cameras shall be transmission control protocol (TCP) capable of being accessed through the internet.

(c) The video surveillance system shall at all times be able to effectively and clearly record images of the area under surveillance.

(d) Each camera shall be permanently mounted and in a fixed location. Each camera shall be placed in a location that allows the camera to clearly record activity occurring within 20 feet of all points of entry and exit on the licensed premises, and allows for the clear and certain identification of any person and activities in all areas required to be filmed under subsection (e).

(e) Areas that shall be recorded on the video surveillance system include the following:

(1) Areas where cannabis goods are weighed, packed, stored, loaded, and unloaded for transportation, prepared, or moved within the premises;

(2) Limited-access areas;

(3) Security rooms;

(4) Areas storing a surveillance-system storage device with at least one camera recording the access points to the secured surveillance recording area; and

(5) Entrances and exits to the premises, which shall be recorded from both indoor and outdoor vantage points.

(f) Retailers shall also record point-of-sale areas and areas where cannabis goods are displayed for sale on the video surveillance system. At each point-of-sale location, camera placement must allow for the recording of the facial features of any person purchasing or selling cannabis goods, or any person in the retail area, with sufficient clarity to determine identity.

(g) Cameras shall record continuously 24 hours per day and at a minimum of 15 frames per second (FPS).

(h) The physical media or storage device on which surveillance recordings are stored shall be secured in a manner to protect the recording from tampering or theft.

(i) Surveillance recordings shall be kept for a minimum of 90 days.

(j) Surveillance recordings are subject to inspection by the Bureau, and shall be kept in a manner that allows the Bureau to view and obtain copies of the recordings at the licensed premises immediately upon request. The licensee shall also send or otherwise provide copies of the recordings to the Bureau upon request within the time specified by the Bureau.

(k) Recorded images shall clearly and accurately display the time and date. Time is to be measured in accordance with the United States National Institute Standards and Technology standards.

(l) The video surveillance system shall be equipped with a failure notification system that provides notification to the licensee of any interruption or failure of the video surveillance system or video surveillance-system storage device.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5045. Security Personnel**

A retail licensee or microbusiness licensee that is engaged in retail sale shall hire or contract for security personnel to provide security services for the licensed retail premises. All security personnel hired or contracted for by the licensee shall comply with Chapters 11.4 and 11.5 of Division 3 of the Business and Professions Code.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5046. Locks**

A licensee shall ensure that the limited-access areas described in section 5042 of this division can be securely locked using commercial-grade, nonresidential door locks. A licensee shall also use commercial-grade, nonresidential door locks on all points of entry and exit to the licensed premises.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5047. Alarm System**

(a) A licensee shall maintain an alarm system as defined in Business and Professions Code section 7590.1(n) at the licensed premises.

(b) A licensee shall ensure a licensed alarm company operator or one or more of its registered alarm agents installs, maintains, monitors, and responds to the alarm system.

(c) Upon request, a licensee shall make available to the Bureau all information related to the alarm system, monitoring, and alarm activity.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**Article 6. Track and Trace Requirements**

**§ 5048. Track and Trace System**

(a) A licensee shall create and maintain an active and functional account within the track and trace system prior to engaging in any commercial cannabis activity, including the purchase, sale, test, packaging, transfer, transport, return, destruction, or disposal, of any cannabis goods.

(b) A licensee shall designate one individual owner as the track and trace system account manager. The account manager may authorize additional owners or employees as track and trace system users and shall ensure that each user is trained on the track and trace system prior to its access or use.

(1) The account manager shall attend and successfully complete all required track and trace system training, including any orientation and continuing education.

(2) If the account manager did not complete the required track and trace system training prior to receiving their annual license, the account manager shall sign up for and complete state mandated training, as prescribed by the Bureau, within five business days of license issuance.

(d) The account manager and each user shall be assigned a unique log-on, consisting of a username and password. The account manager or each user accessing the track and trace system shall only do so under his or her assigned log-on, and shall not use or access a log-on of any other individual. No account manager or user shall share or transfer his or her log-on, username, or password, to be used by any other individual for any reason.

(e) The account manager shall maintain a complete, accurate, and up-to-date list of all track and trace system users, consisting of their full names and usernames.

(f) A licensee shall monitor all compliance notifications from the track and trace system, and timely resolve the issues detailed in the compliance notification.

(1) A licensee shall keep a record, independent of the track and trace system, of all compliance notifications received from the track and trace system, and how and when compliance was achieved.

(2) If a licensee is unable to resolve a compliance notification within three business days of receiving the notification, the licensee shall notify the Bureau immediately.

(g) A licensee is accountable for all actions its owners or employees take while logged into or using the track and trace system, or otherwise while conducting track and trace activities.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26067, 26070, 26160 and 26161, Business and Professions Code.

**§ 5049. Track and Trace Reporting**

(a) A licensee shall record in the track and trace system all commercial cannabis activity, including:

(1) Packaging of cannabis goods.

(2) Sale of cannabis goods.

(3) Transportation of cannabis goods to a licensee.

(4) Receipt of cannabis goods.

(5) Return of cannabis goods.

(6) Destruction and disposal of cannabis goods.

(7) Laboratory testing and results.

(8) Any other activity as required pursuant to this division, or by any other licensing authority.

(b) The following information shall be recorded for each activity entered in the track and trace system:

(1) Name and type of the cannabis goods.

(2) Unique identifier of the cannabis goods.

(3) Amount of the cannabis goods, by weight or count.

(4) Date and time of the activity or transaction.

(5) Name and license number of other licensees involved in the activity or transaction.

(6) If the cannabis goods are being transported:

(A) The licensee shall transport pursuant to a shipping manifest generated through the track and trace system, that includes items (1) through (5) of this subsection, as well as:

(i) The name, license number, and premises address of the originating licensee.

(ii) The name, license number, and premises address of the licensee transporting the cannabis goods.

(iii) The name, license number, and premises address of the destination licensee receiving the cannabis goods into inventory or storage.

(iv) The date and time of departure from the licensed premises and approximate date and time of departure from each subsequent licensed premises, if any.

(v) Arrival date and estimated time of arrival at each licensed premises.

(vi) Driver license number of the personnel transporting the cannabis goods, and the make, model, and license plate number of the vehicle used for transport.

(B) Upon pick-up or receipt of cannabis goods for transport, storage, or inventory, a licensee shall ensure that the cannabis goods received are as described in the shipping manifest, and shall record acceptance and acknowledgment of the cannabis goods in the track and trace system.

(C) If there are any discrepancies between the type or quantity specified in the shipping manifest and the type or quantity received by the licensee, the licensee shall record and document the discrepancy in the track and trace system and in any relevant business record.

(7) If cannabis goods are being destroyed or disposed of, the licensee shall record in the track and trace system the following additional information:

(A) The name of the employee performing the destruction or disposal.

(B) The reason for destruction or disposal.

(C) The name of the entity being used to collect and process cannabis waste, pursuant to section 5055 of this division.

(8) Description for any adjustments made in the track and trace system, including, but not limited to:

(A) Spoilage or fouling of the cannabis goods.

(B) Any event resulting in exposure or compromise of the cannabis goods.

(9) Any other information as required pursuant to this division, or by any other applicable licensing authorities.

(c) Unless otherwise specified, all transactions must be entered into the track and trace system within 24 hours of occurrence.

(d) Licensees shall only enter and record complete and accurate information into the track and trace system, and shall correct any known errors entered into the track and trace system immediately upon discovery.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26067, 26070, 26160 and 26161, Business and Professions Code.

**§ 5050. Loss of Access**

(a) If at any point a licensee loses access to the track and trace system for any reason, the licensee shall prepare and maintain comprehensive records detailing all commercial cannabis activities that were conducted during the loss of access.

(b) The licensee shall both document and notify the Bureau immediately:

(1) When access to the system is lost;

(2) When access to the system is restored; and

(3) The cause for the loss of access.

(c) Once access is restored, all commercial cannabis activity that occurred during the loss of access shall be entered into the track and trace system within three business days of access being restored.

(d) A licensee shall not transport, transfer or deliver any cannabis goods until such time as access is restored and all information recorded in the track and trace system.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26067, 26070, 26160 and 26161, Business and Professions Code.

**§ 5051. Track and Trace System Reconciliation**

(a) In addition to other inventory reconciliation requirements under this division, a licensee shall reconcile the physical inventory of cannabis goods at the licensed premises with the records in the track and trace database at least once every 14 days.

(b) If a licensee finds a discrepancy between its physical inventory and the track and trace system database, the licensee shall conduct an audit, and notify the Bureau of any reportable activity pursuant to section 5036.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26067, 26070, 26160 and 26161, Business and Professions Code.

**§ 5052. Temporary Licenses; Licensees in Operation at Time of Licensure**

(a) A licensee operating under a temporary license issued pursuant to section 5001 is not required to record commercial cannabis activity in the track and trace system as otherwise required by this article.

(b) Temporary licensees shall track and record all cannabis commercial activities and information required pursuant to this division and any other provision of law, at a minimum, on paper receipts, invoices, or manifests.

(c) Any commercial cannabis activity conducted between annual license holders shall be recorded in the track and trace system.

(d) Any licensee in operation at the time the annual license is issued shall enter all inventory into the track and trace system no later than 30 days after the track and trace system account manager attends the training required pursuant to section 5048.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26050.1, 26067, 26070, 26160 and 26161, Business and Professions Code.

**Article 7. Returns and Destruction**

**§ 5053. Returns Between Licensees**

(a) If a licensee discovers that a manufactured cannabis good that was purchased from another licensee is defective, the purchasing licensee may return the cannabis good to the selling licensee only in exchange for a non-defective version of the same type of cannabis good or in exchange for a cannabis good of equal value.

(b) Except as provided in subsection (a) of this section, a licensee shall not return cannabis goods purchased from another licensee.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26013 and 26070, Business and Professions Code.

**§ 5054. Destruction of Cannabis Products Prior to Disposal**

No cannabis goods shall be disposed of as cannabis waste pursuant to section 5055 of this division unless the cannabis goods have been removed from their packaging and rendered unrecognizable and unusable.

Authority: Section 26013, Business and Professions Code. Reference: Sections 260013 and 26070, Business and Professions Code.

**§ 5055. Cannabis Waste Management**

(a) A licensee may not sell cannabis waste.

(b) Licensees shall comply with all applicable waste management laws including, but not limited to, Division 30 of the Public Resources Code.

(c) A licensee shall dispose of cannabis waste in a secured waste receptacle or in a secured area on the licensed premises. For the purposes of this section, "secure waste receptacle" or "secured area" means that physical access to the receptacle or area is restricted to the licensee and its employees and the local agency, or waste hauler franchised or contracted by a local agency. Public access to the designated receptacle or area is prohibited.

(d) If a licensee is composting cannabis waste on the licensed premises, a licensee shall do so in compliance with title 14, California Code of Regulations, chapter 3.1 (commencing with Section 17850).

(e) If a local agency, or waste hauler permitted by a local agency, is being used to collect and process cannabis waste, a licensee shall do all the following:

(1) Provide the Bureau with the following information for the local agency, or waste hauler franchised or contracted by a local agency, who will collect and process the licensee's cannabis waste;

(A) Name of local agency providing waste hauling services, if applicable;

(B) Company name of the local agency franchised or contracted or permitted waste hauler, if applicable;

(C) Company business address; and

(D) Name of the primary contact person at the company and contact person's phone number.

(2) Obtain documentation from the entity hauling the waste that indicates the date and time of each collection of cannabis waste at the licensed premises; and

(3) Obtain a copy of the certified weight ticket or other documentation prepared by the entity hauling the waste confirming receipt of the cannabis waste at one, or more, of the following solid waste facilities:

(A) A manned, fully permitted solid waste landfill or transformation facility;

(B) A manned, fully permitted composting facility or manned composting operation;

(C) A manned, fully permitted in-vessel digestion facility or manned in-vessel digestion operation;

(D) A manned, fully permitted transfer/processing facility or manned transfer/processing operation; or

(E) A manned, fully permitted chip and grind operation.

(f) If a licensee is self-hauling cannabis waste to one, or more, of the solid waste facilities in subsection (e)(3) of this section, a licensee shall obtain for each delivery of cannabis waste by the licensee a copy of a certified weight ticket or receipt documenting delivery from the solid waste facility. Only the licensee or its employees may transport self-hauled cannabis waste.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26013 and 26070, Business and Professions Code.

## Chapter 2. DISTRIBUTORS

### § 5300. Non-Cannabis Distribution Activities

A distributor shall not store non-cannabis goods or non-cannabis accessories that are to be sold to another party on any licensed premises. Additionally, a distributor shall not distribute non-cannabis goods or non-cannabis accessories at a licensed premises. For the purposes of this section, non-cannabis goods are any goods that do not meet the definition of cannabis goods as defined in section 5000(c) of this division.

Authority: Sections 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5301. Storage-Only Services**

A distributor may provide cannabis goods storage-only services to a licensed cultivator, manufacturer, microbusiness, nonprofit, or another distributor, unrelated to the quality assurance and laboratory testing processes.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5302. Storage of Batches for Testing**

(a) A distributor shall ensure that all cannabis goods batches are stored separately and distinctly from other cannabis goods batches on the distributor's premises.

(b) A distributor shall ensure a label with the following information is physically attached to each container of each batch:

(1) The name and license number of the manufacturer or cultivator who provided the batch;

(2) The date of entry into the distributor's storage area;

(3) The unique identifiers and batch number associated with the batch;

(4) A description of the cannabis goods with enough detail to easily identify the batch;

(5) The weight of or quantity of units in the batch; and

(6) The best-by, sell-by, or expiration date of the batch, if any.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26110 and 26120, Business and Professions Code.

**§ 5303. Packaging and Labeling**

(a) A distributor may package, re-package, label, and re-label cannabis for retail sale.

(b) A distributor shall not package, re-package, label, or re-label manufactured cannabis products except when the distributor also holds a manufacturing license and is packaging, re-packaging, labeling, or re-labeling its own manufactured cannabis products.

(c) Notwithstanding subsection (b) of this section, if it is determined during laboratory testing that a manufactured product is labeled with the incorrect amount of THC per package or serving but is within the THC limits for sale, the distributor may re-label the package with the accurate THC amount.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26013 and 26120, Business and Professions Code.

**§ 5304. Testing Arrangements**

After taking physical possession of a cannabis goods batch, the distributor shall contact a testing laboratory and arrange for a laboratory employee to come to the distributor's licensed premises to select a representative sample for laboratory testing.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26110, Business and Professions Code.

**§ 5305. Testing Sample**

(a) The distributor shall ensure that the batch size from which the sample is taken meets the requirements of this division.

(b) A distributor or an employee of the distributor shall be physically present to observe the laboratory employee obtain the sample of cannabis goods for testing and shall ensure that the increments are taken from throughout the batch.

(c) The sampling shall be video recorded with the batch number stated at the beginning of the video and a visible time and date indication on the video recording footage. The video recordings shall be maintained for 180 days.

(d) After the sample has been selected, both the distributor and the laboratory employee shall sign and date the chain of custody form pursuant to section 5709 of this division, attesting to the sample selection having occurred.

(e) A distributor shall not assist the laboratory employee nor touch the cannabis goods or the sampling equipment while the laboratory employee is obtaining the sample.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26104 and 26110, Business and Professions Code.

**§ 5306. Laboratory Testing Results**

(a) A sample "passes" a laboratory test when the sample meets specifications in chapter 6 of this division.

(b) When a batch from a manufactured or harvest batch passes, the cannabis goods may be transported to one or more retailers.

(c) A sample "fails" a laboratory test when the sample does not meet specifications in chapter 6 of this division.

(d) If a failed sample was collected from a batch and the batch could be remediated pursuant to section 5727 of this division, a distributor may transport or arrange for the transportation of the batch to a cultivator or manufacturer for remediation.

(e) A distributor shall destroy a batch that failed laboratory testing and cannot be remediated pursuant to section 5727 of this division.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070, 26104 and 26110, Business and Professions Code.

**§ 5307. Quality-Assurance Review**

When a distributor receives a certificate of analysis stating that the sample meets specifications required by law, the distributor shall ensure the following before transporting the cannabis goods to one or more retailers:

(a) The certificate of analysis the distributor received from the testing laboratory is the certificate of analysis that corresponds to the batch;

(b) The label on the cannabis goods is consistent with the certificate of analysis regarding cannabinoid content and contaminants required to be listed by law;

(c) The packaging complies with applicable packaging laws including, but not limited to, Business and Professions Code section 26120;

(d) The packaging is tamper-evident. "Tamper-evident" means a one-time-use seal is affixed to the opening of the package, allowing a person to recognize whether or not the package has been opened;

(e) The weight or count of the cannabis batch comports with that in the track and trace system. A distributor shall use scales as required by the Act; and

(f) All events prior to receipt have been entered into the track and trace system.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070, 26110 and 26120, Business and Professions Code.

**§ 5308. Insurance Requirements**

(a) An applicant for a distributor license shall provide the Bureau with a certificate of insurance that shows the types of insurance coverage and minimum amounts that have been secured as required by this section, and documentation establishing compliance with subsection (d) of this section.

(b) A distributor licensee shall at all times carry and maintain commercial general liability insurance in the aggregate in an amount no less than $2,000,000 and in an amount no less than $1,000,000 for each loss.

(c) A distributor licensee shall maintain the insurance required in subsection (b) from an insurance company that is:

(1) A non-admitted insurer that meets the requirements of Insurance Code section 1765.1 or 1765.2, and the insurance is placed pursuant to Insurance Code section 1763 and through a surplus line broker licensed under Insurance Code section 1765;

(2) An insurer qualified to do business in California by the Secretary of State and authorized by the Insurance Commissioner to write the liability and property classes of insurance as defined by Insurance Code sections 102, 103, 107, 114, 108, and 120; or

(3) A registered risk retention group compliant with the California Risk Retention Act of 1991. (See California Insurance Code sections 125-140.)

(d) Admitted insurers and risk retention groups must show proof of capitalization in the amount of at least $10,000,000.

(e) A distributor licensee shall notify the Bureau in writing within 10 calendar days of a lapse in insurance.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5309. Inventory Reconciliation**

(a) A distributor shall reconcile all inventories of cannabis goods at least once every 14 days.

(b) A distributor shall keep an inventory log containing the following information for each batch:

(1) The name and license number of the manufacturer or cultivator who provided the batch;

(2) The date of entry into the distributor's storage area;

(3) The unique identifiers and batch number associated with the batch;

(4) A description of the cannabis goods with enough detail to easily identify the batch;

(5) The weight of or quantity of units in the batch;

(6) The best-by, sell-by, or expiration date of the batch, if any; and

(7) Where on the premises the batch is kept.

(c) If a distributor finds a discrepancy between the inventory of stock and the inventory log or track and trace system that is outside of normal weight loss caused by moisture loss, the distributor shall commence a full audit of the batch in which the discrepancy was found.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070 and 26160, Business and Professions Code.

**§ 5310. Records**

(a) In addition to the records required by section 5037 of this division, a distributor shall maintain the following records:

(1) Records relating to branding, packaging and labeling;

(2) Inventory logs and records;

(3) Transportation bills of lading and shipping manifests for completed transports and for cannabis goods in transit;

(4) Vehicle and trailer ownership records;

(5) Quality-assurance records;

(6) Records relating to destruction of cannabis goods;

(7) Laboratory-testing records;

(8) Warehouse receipts;

(9) Records relating to tax payments collected and paid under Sections 34011 and 34012 of the Revenue and Tax Code.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26110 and 26160, Business and Professions Code.

**§ 5311. Requirements for the Transportation of Cannabis Goods**

The following requirements apply when transporting cannabis goods between licensees or licensed premises:

(a) Transportation shall only be conducted by persons holding a distributor license under the Act, or employees of those persons.

(b) All vehicles transporting cannabis goods for hire shall be required to have a motor carrier permit pursuant to Chapter 2 (commencing with Section 34620) of Division 14.85 of the Vehicle Code.

(c) Transportation by means of aircraft, watercraft, drone, rail, human powered vehicle, and unmanned vehicle is prohibited.

(d) Cannabis goods shall only be transported inside of a vehicle or trailer and shall not be visible or identifiable from outside of the vehicle or trailer.

(e) Cannabis goods shall be locked in a box, container, or cage that is secured to the inside of the vehicle or trailer.

(f) While left unattended, vehicles and trailers shall be locked and secured.

(g) A distributor shall not leave a vehicle or trailer containing cannabis goods unattended in a residential area or parked overnight in a residential area.

(h) At a minimum, a distributor shall have a vehicle alarm system on all transport vehicles and trailers. Motion detectors, pressure switches, duress, panic, and hold-up alarms may also be used.

(i) Packages or containers holding cannabis goods shall not be tampered with, or opened, during transport.

(j) A distributor transporting cannabis goods shall only travel between licensees shipping or receiving cannabis goods and its own licensed premises when engaged in the transportation of cannabis goods. The distributor may transport multiple shipments of cannabis goods at once in accordance with applicable laws. A distributor shall not deviate from the travel requirements described in this section, except for necessary rest, fuel, or vehicle repair stops.

(k) When a distributor holds both an A-license and an M-license, medicinal and adult-use cannabis goods may be transported in the same vehicle only if the cannabis goods are clearly identified and marked as "A" for adult-use cannabis goods, or "M" for medicinal cannabis goods both on the physical packaging of the cannabis goods and on the shipping manifest. While in transport, the medicinal and adult-use cannabis goods shall be placed in separate boxes or containers in the vehicle. Under no circumstances may non-cannabis goods, except for cannabis accessories as defined in Business and Professions Code section 26001(g), be transported with cannabis goods.

(l) Vehicles and trailers transporting cannabis goods are subject to inspection by the Bureau at any licensed premises or during transport at any time.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5312. Required Transport Vehicle Information**

(a) In addition to the information required in section 5314 of this division, any distributor who will be or is transporting cannabis goods shall provide the following information to the Bureau:

(1) Proof of ownership or a valid lease for each vehicle and trailer used to transport cannabis goods;

(2) The year, make, model, license plate number, and numerical Vehicle Identification Number (VIN) for each vehicle and trailer used to transport cannabis goods; and

(3) Proof of insurance for each vehicle and trailer used to transport cannabis goods.

(b) The distributor shall provide the Bureau with the information required by this section in writing for any new vehicle or trailer that will be used to transport cannabis goods prior to using the vehicle or trailer to transport cannabis goods.

(c) The distributor shall provide the Bureau with any changes to the information required by this section in writing within 30 calendar days.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5313. Transport Personnel Requirements**

(a) No person under the age of 21 years old shall be in a commercial vehicle or trailer transporting cannabis goods; and

(b) Only a licensee or an employee of the distributor shall be in a vehicle while transporting cannabis goods.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5314. Shipping Manifest**

(a) Prior to transporting cannabis goods, a distributor shall generate a shipping manifest through the track and trace system for the following activities:

(1) Testing and sampling;

(2) Sale of cannabis goods to a licensee;

(3) Destruction or disposal of cannabis goods; and

(4) Any other activity, as required pursuant to this division, or by any other licensing authority.

(b) The distributor shall transmit the shipping manifest to the Bureau and the licensee that will receive the cannabis goods prior to transporting the cannabis goods.

(c) The distributor shall ensure and verify that the cannabis goods being taken into possession for transport at the originating licensed premises are as described and accurately reflected in the shipping manifest.

(1) The distributor shall not take into possession or transport:

(A) Any cannabis goods that are not on the shipping manifest; or

(B) Any cannabis goods that are less than or greater than the amount reflected on the shipping manifest.

(2) The distributor is responsible for any discrepancies between the shipping manifest and the cannabis goods in its possession during transport, and subject to any enforcement or disciplinary action related to such discrepancy.

(3) A distributor shall not void or change a shipping manifest after departing from the originating licensed premises.

(d) A shipping manifest shall accompany every transport of cannabis goods.

(e) Notwithstanding subsection (a) of this section, if a transporting distributor has not obtained access to the track and trace system, the distributor shall complete the shipping manifest outside of the track and trace system and transmit it to the Bureau and the licensee receiving the shipment by electronic mail.

(f) If the transporting distributor has access to the track and trace system and the licensee receiving the shipment has not obtained access to the track and trace system, the distributor shall complete the shipping manifest in the track and trace system and transmit it to the Bureau. However, the distributor shall send a copy to the licensee receiving the shipment by electronic mail.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26067 and 26070, Business and Professions Code.

**§ 5315. Distributor Transport Only License**

(a) A distributor transport only licensee shall be authorized to engage in the transport of cannabis goods between licensees.

(b) Notwithstanding subsection (a) of this section, a distributor transport only licensee shall not be authorized to transport cannabis goods to the premises of a retailer, except when the licensee is transporting only immature plants and seeds from a licensed nursery to a licensed retailer.

(c) A complete application for a distributor transport only license shall include all the information required in an application for a Type 11-Distributor license.

(d) The licensing fee for a distributor transport only license will be based in part upon whether the licensee intends to transport only cannabis goods that the licensee has cultivated or manufactured (self-distribution), or whether the licensee intends to transport cannabis goods cultivated or manufactured by other licensees.

(e) A distributor transport only licensee shall comply with all of the requirements for a holder of a Type 11-Distributor license, except for those related to quality assurance and testing.

(f) A distributor transport only licensee shall not hold title to any cannabis goods unless the licensee also holds a state-issued cultivation, manufacturing, retailer, or microbusiness license.

(g) Holding a distributor transport only license shall not authorize a licensee to:

(1) Engage in the delivery of cannabis goods as defined in Business and Professions Code section 26001(p);

(2) Engage in the wholesale, destruction, packaging, labeling, or storing of cannabis goods; or

(3) Arrange for the testing of cannabis goods by a testing laboratory.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26012, 26013 and 26070, Business and Professions Code.

**Chapter 3. RETAILERS**

**§ 5400. Access to Retailer Premises**

(a) Access to the licensed premises of an A-retailer licensee shall be limited to individuals who are at least 21 years of age.

(b) Access to the licensed premises of an M-retailer licensee shall be limited to individuals who are at least 18 years of age and have a valid physician's recommendation.

(c) If a licensed premises is shared by an A-license and an M-license pursuant to section 5025 of this division, the licensee may allow persons identified in subsections (a) and (b) above to access the premises.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26012, 26070 and 26140, Business and Professions Code.

**§ 5401. Limited-Access Areas**

(a) A retailer shall establish limited-access areas and permit only authorized individuals to enter the limited-access areas.

(b) Authorized individuals include individuals employed by the retailer as well as any outside vendors, contractors, or other individuals conducting business that requires access to the limited-access area.

(c) An individual in the limited-access area who is not employed by the retailer shall be escorted by an employee of the licensee at all times within the limited-access area.

(d) An individual who enters the limited-access area shall be at least 21 years of age.

(e) A retailer shall maintain a log of all authorized individuals who are not employees of the retailer who enter the limited-access area. These logs shall be made available to the Bureau upon request.

(f) A retailer shall not receive consideration or compensation for permitting an individual to enter the limited-access area.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070 and 26140, Business and Professions Code.

**§ 5402. Retail Area**

(a) Individuals shall be granted access to the retail area to purchase cannabis goods only after the retailer or an employee of the retailer has verified that the individual is at least 21 years of age and has a valid proof of identification, or that the individual is at least 18 years of age and has valid proof of identification and a valid physician's recommendation for himself or herself or for a person for whom he or she is a primary caregiver.

(b) Acceptable forms of identification include the following:

(1) A document issued by a federal, state, county, or municipal government, or a political subdivision or agency thereof, including, but not limited to, a valid motor vehicle operator's license, that contains the name, date of birth, physical description, and photo of the person;

(2) A valid identification card issued to a member of the Armed Forces that includes a date of birth and a photo of the person; or

(3) A valid passport issued by the United States or by a foreign government.

(c) A valid proof of identification must clearly indicate the age or birthdate of the individual.

(d) The retailer or at least one employee shall be physically present in the retail area at all times when individuals who are not employees of the retailer are in the retail area.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070 and 26140, Business and Professions Code.

**§ 5403. Hours of Operation**

(a) A retailer shall sell and deliver cannabis goods only between the hours of 6:00 a.m. Pacific Time and 10:00 p.m. Pacific Time.

(b) At any time the premises is not open for retail sales, the retailer shall ensure that:

(1) The premises is securely locked with commercial-grade, nonresidential door locks;

(2) The premises is equipped with an active alarm system, which shall be activated when the retailer or its employees are not on the licensed premises; and

(3) Only employees and contractors of the retailer are allowed to enter the premises.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code

**§ 5404. Retail Customers**

(a) A retailer shall only sell adult-use cannabis goods to individuals who are at least 21 years of age, and medicinal cannabis goods to individuals at least 18 years of age who possess a valid physician's recommendation for himself or herself or a person for whom he or she is a primary caregiver.

(b) A retailer shall verify the identity and age, and physician's recommendation if applicable, of a customer as required by section 5402(a) of this division.

Authority: Section 26013, Business and Professions Code. Reference: Section 26140, Business and Professions Code.

**§ 5405. Cannabis Goods Display**

(a) Cannabis goods for inspection and sale shall only be displayed in the retail area.

(b) The retailer shall not display cannabis goods in a place visible from outside the licensed premises.

(c) Cannabis goods may be removed from their packaging and placed in containers to allow for customer inspection. The containers shall not be readily accessible to customers without assistance of retailer personnel. A container must be provided to the customer by the retailer or its employees, who shall remain with the customer at all times that the container is being inspected by the customer.

(d) Cannabis goods removed from their packaging for display shall not be sold, shall not be consumed, and shall be destroyed pursuant to section 5054 of this division when the cannabis goods are no longer used for display.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5406. Cannabis Goods for Sale**

A retailer shall not make any cannabis goods available for sale or delivery to a customer unless:

(a) The cannabis goods were received from a licensed distributor;

(b) The retailer has verified that the cannabis goods have not exceeded their expiration or sell-by date if one is provided; and

(c) In the case of manufactured cannabis products, the product complies with all requirements of Business and Professions Code section 26130 and all other relevant laws.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§5407. Sale of Non-Cannabis Products on Premises**

A retailer may sell non-cannabis products on a licensed premises if the licensee remains in compliance with any city, county, and state laws or regulations related to those products. This provision excludes alcohol and alcohol products and tobacco and tobacco products from sale at any licensed premises.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26054 and 26070, Business and Professions Code.

**§ 5408. Live Plants**

(a) A retailer shall only sell live, immature cannabis plants and seeds if all of the following requirements are met:

(1) The plant is not flowering;

(2) The plant or seed was purchased from a nursery that holds a valid Type 4-Cultivation; Nursery license under the Act; and

(3) A label is affixed to the plant or package containing any seeds which states "This product has not been tested pursuant to the Medicinal and Adult-Use Cannabis Regulation and Safety Act."

(b) A retailer may not sell any other live plants.

(c) A retailer shall not apply nor use any pesticide, nor cause any pesticide to be applied nor used, on live plants.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070 and 26100, Business and Professions Code.

**§ 5409. Daily Limits**

(a) A retailer shall not sell more than the following amounts to a single adult-use cannabis customer in a single day:

(1) 28.5 grams of non-concentrated cannabis.

(2) 8 grams of concentrated cannabis as defined in Business and Professions Code section 26001, including concentrated cannabis contained in cannabis products.

(3) 6 immature cannabis plants.

(b) A retailer shall not sell more than the following amounts to a single medicinal cannabis patient, or to a patient's primary caregiver purchasing medicinal cannabis on behalf of the patient, in a single day:

(1) 8 ounces of medicinal cannabis as defined in section 11362.77 of the Health and Safety Code.

(2) 12 immature cannabis plants.

(c) If a valid physician's recommendation contains a different amount than the limits listed in this section, the medicinal cannabis customer may purchase an amount of medicinal cannabis consistent with the patient's needs as recommended by a physician.

Authority: Section 26013, Business and Professions Code. Reference: Section 26012, Business and Professions Code; and Sections 11362.1 and 11362.77, Health and Safety Code.

**§ 5410. Customer Return of Cannabis Goods**

(a) For the purposes of this section, "customer return" means a customer's return of cannabis goods that were purchased from a retailer, back to the retailer the cannabis goods were purchased from.

(b) A retailer may accept customer returns of cannabis goods that were previously sold to a customer.

(c) A retailer shall not resell cannabis goods that have been returned.

(d) A retailer shall treat any cannabis goods abandoned on the retailer premises as a customer return.

(e) A retailer shall destroy all cannabis goods that have been returned to the retailer by a customer, in accordance with sections 5054 and 5055 of this division.

Authority: Section 26013, Business and Professions Code. Reference: Section 26012, Business and Professions Code.

**§ 5411. Free Cannabis Goods**

(a) A retailer shall not provide free cannabis goods to any person. A retailer shall not allow individuals who are not employed by the retailer to provide free cannabis goods to any person on the licensed premises.

(b) Notwithstanding subsection (a) of this section, in order to provide access to medicinal cannabis patients who have difficulty accessing medicinal cannabis goods, a licensee who holds a Type 10-Retailer M-license, a Type 9-Retailer Non-storefront-M license, or a Type 12-Microbusiness M-license that allows for retail sales may provide free medicinal cannabis goods if all of the following criteria are met:

(1) Free cannabis goods are provided only to a medicinal cannabis patient or primary caregiver for the patient in possession of a valid identification card issued under Section 11362.71 of the Health and Safety Code.

(2) The cannabis goods comply with all applicable laboratory testing requirements under this division.

(3) Prior to being provided to the patient or primary caregiver, the cannabis goods have been properly recorded in the track and trace system as belonging to the retailer.

(4) The cannabis goods shall not leave the licensed premises unless placed in an opaque package as required for purchased cannabis goods under Business and Professions Code section 26070.1.

(5) The cannabis goods shall be applied toward the daily purchase limit for a medicinal cannabis customer pursuant to section 5409 of this division.

(6) The event shall be properly recorded in the retailer's inventory records and the track and trace system.

(c) In addition to the provision of free cannabis goods in subsection (b) of this section, a licensee may donate cannabis goods and the use of equipment in compliance with any compassionate use, equality, or other similar program administered by a local jurisdiction.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26013, 26153 and 26160, Business and Professions Code.

**§ 5412. Packaging and Labeling**

(a) A retailer shall not accept, possess, or sell cannabis goods that are not packaged as they will be sold at final sale, in compliance with this division.

(b) A retailer shall not package or label cannabis goods.

Authority: Section 26013, Business and Professions Code. Reference: Section 26120, Business and Professions Code.

**§ 5413. Exit Packaging**

Cannabis goods purchased by a customer shall not leave the retailer's premises unless the goods are placed in an opaque exit package.

Authority: Section 26013, Business and Professions Code. Reference: Section 26120, Business and Professions Code.

**§ 5414. Type 9- Non-Storefront Retailer**

(a) A Type 9-Non-Storefront Retailer licensee shall be authorized to conduct retail cannabis sales exclusively by delivery as defined in Business and Professions Code section 26001(p).

(b) A complete application for a Type 9-Non-Storefront Retailer license shall include all the information required in an application for a Type 10-Retailer license.

(c) A Type 9-Non-Storefront Retailer licensee shall comply with all the requirements applicable to Type 10-Retailer licensees, except for those provisions related to public access to the premises.

(d) The licensed premises of a Type 9-Non-Storefront Retailer licensee shall be closed to the public.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26012 and 26070, Business and Professions Code.

**§ 5415. Delivery**

(a) All deliveries of cannabis goods shall be performed by a delivery employee of a retailer.

(b) Each delivery employee of a retailer shall be at least 21 years of age.

(c) All deliveries of cannabis goods shall be made in person. A delivery of cannabis goods shall not be made through the use of an unmanned vehicle.

(d) The process of delivery begins when the delivery employee leaves the retailer's licensed premises with the cannabis goods for delivery. The process of delivering ends when the delivery employee returns to the retailer's licensed premises after delivering the cannabis goods to the customer(s).

(e) A delivery employee of a retailer shall, during deliveries, carry a copy of the retailer's current license, the employee's government-issued identification, and an identification badge provided by the employer pursuant to section 5043 of this division.

(f) A retailer shall maintain an accurate list of the retailer's delivery employees.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070 and 26090, Business and Professions Code.

**§ 5416. Delivery to a Physical Address**

(a) A retailer may only deliver cannabis goods to a physical address in California.

(b) A retailer delivery employee shall not leave the State of California while possessing cannabis goods.

(c) A retailer shall not deliver cannabis goods to an address located on publicly owned land or any address on land or in a building leased by a public agency. This prohibition applies to land held in trust by the United States for a tribe or an individual tribal member unless the delivery is authorized by and consistent with applicable tribal law.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070 and 26090, Business and Professions Code.

**§ 5417. Methods of Delivery**

(a) A retailer's delivery employee, carrying cannabis goods for delivery, shall only travel in an enclosed motor vehicle operated by a delivery employee of the licensee.

(b) While carrying cannabis goods for delivery, a retailer's delivery employee shall ensure the cannabis goods are not visible to the public.

(c) A retailer's delivery employee shall not leave cannabis goods in an unattended motor vehicle unless the motor vehicle is locked and equipped with an active vehicle alarm system.

(d) A vehicle used for the delivery of cannabis goods shall be outfitted with a dedicated Global Positioning System (GPS) device for identifying the geographic location of the delivery vehicle. A dedicated GPS device must be owned by the licensee and used for delivery only. The device shall be either permanently or temporarily affixed to the delivery vehicle and shall remain active and inside of the delivery vehicle at all times during delivery. At all times, the retailer shall be able to identify the geographic location of all delivery vehicles that are making deliveries for the retailer and shall provide that information to the Bureau upon request.

(e) Upon request, a retailer shall provide the Bureau with information regarding any motor vehicle used for the delivery of cannabis goods, including the vehicle's make, model, color, Vehicle Identification Number, license plate number and Department of Motor Vehicles registration information.

(f) Any motor vehicle used by a retailer to deliver cannabis goods is subject to inspection by the Bureau. Vehicles used to deliver cannabis goods may be stopped and inspected by the Bureau at any licensed premises or during delivery.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070 and 26090, Business and Professions Code.

**§ 5418. Cannabis Goods Carried During Delivery**

While making deliveries, a retailer's delivery employee shall not carry cannabis goods valued in excess of $3,000 at any time. This value shall be determined using the current retail price of all cannabis goods carried by the delivery employee.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070 and 26090, Business and Professions Code.

**§ 5419. Cannabis Consumption During Delivery**

A retailer's delivery employees shall not consume cannabis goods while delivering cannabis goods to customers.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070 and 26090, Business and Professions Code.

**§ 5420. Delivery Request Receipt**

A retailer shall prepare a delivery request receipt for each delivery of cannabis goods.

(a) The delivery request receipt shall contain the following:

(1) The name and address of the retailer;

(2) The first name and employee number of the retailer's delivery employee who delivered the order;

(3) The first name and employee number of the retailer's employee who prepared the order for delivery;

(4) The first name of the customer and a retailer-assigned customer number for the person who requested the delivery;

(5) The date and time the delivery request was made;

(6) The delivery address;

(7) A detailed description of all cannabis goods requested for delivery. The description shall include the weight, volume, or any other accurate measure of the amount of all cannabis goods requested;

(8) The total amount paid for the delivery, including any taxes or fees, the cost of the cannabis goods, and any other charges related to the delivery; and

(9) Upon delivery, the date and time the delivery was made, and the signature of the customer who received the delivery.

(b) At the time of the delivery, the delivery employee of the retailer shall provide the customer who placed the order with a copy of the delivery request receipt. The delivery employee shall retain a signed copy of the delivery request receipt for the retailer's records.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070 and 26090, Business and Professions Code.

**§ 5421. Delivery Route**

While making deliveries of cannabis goods, a retailer's delivery employee shall only travel from the retailer's licensed premises to the delivery address; from one delivery address to another delivery address; or from a delivery address back to the retailer's licensed premises. A delivery employee of a retailer shall not deviate from the delivery path described in this section, except for necessary rest, fuel, or vehicle repair stops, or because road conditions make continued use of the route unsafe, impossible, or impracticable.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26070 and 26090, Business and Professions Code.

**§ 5422. Receiving Shipments of Inventory**

(a) A retailer shall receive a shipment of cannabis goods only from a distributor.

(b) A retailer shall accept shipments of cannabis goods only between the hours of 6:00 a.m. Pacific Time and 10:00 p.m. Pacific Time.

(c) During business hours, shipments of cannabis goods shall not enter the premises through an entrance or exit that is available for use by the public.

Authority: Section 26013, Business and Professions Code. Reference: Section 26070, Business and Professions Code.

**§ 5423. Inventory Documentation**

A retailer shall maintain an accurate record of its inventory. A retailer shall provide the Bureau with the record of inventory upon request. A retailer shall keep a record of the following information for all cannabis goods the retailer has in its inventory:

(a) A description of each item such that the cannabis goods can easily be identified;

(b) An accurate measurement of the quantity of the item;

(c) The date and time the cannabis goods were received by the retailer;

(d) The sell-by or expiration date provided on the package of cannabis goods, if any;

(e) The name and license number of the licensee that delivered the cannabis goods to the retailer;

(f) The name and license number of the distributor that provided the cannabis goods to the retailer; and

(g) The price the retailer paid for the cannabis goods, including taxes, delivery costs, and any other costs.

Authority: Section 26013, Business and Professions Code. Reference: Section 26160, Business and Professions Code.

**§ 5424. Inventory Reconciliation**

(a) A retailer shall perform a reconciliation of its inventory at least once every 14 days.

(b) A retailer shall verify that the retailer's physical inventory matches the retailer's records pertaining to inventory.

(c) The result of inventory reconciliation shall be retained in the retailer's records and shall be made available to the Bureau upon request.

(d) If a retailer identifies any evidence of theft, diversion, or loss, the retailer shall notify the Bureau and law enforcement pursuant to section 5036 of this division.

(e) If a significant discrepancy as defined in section 5034 of this division is discovered between a retailer's physical inventory and the retailer's inventory records, the retailer shall notify the Bureau and law enforcement pursuant to section 5036 of this division.

Authority: Section 26013, Business and Professions Code. Reference: Section 26160, Business and Professions Code.

**§ 5425. Record of Sales**

(a) A retailer shall maintain an accurate record of sale for every sale made to a customer.

(b) A record of a medicinal cannabis goods sale shall contain the following information:

(1) The first name and employee number of the retailer employee who processed the sale;

(2) The first name of the customer and a retailer-assigned customer number for the person who made the purchase;

(3) The date and time of the transaction;

(4) A list of all the cannabis goods purchased, including the quantity purchased; and

(5) The total amount paid for the sale including the individual prices paid for each cannabis good purchased and any amounts paid for taxes.

Authority: Section 26013, Business and Professions Code. Reference: Section 26160, Business and Professions Code.

**§ 5426. Records**

All retailer-specific records in this chapter shall be maintained in accordance with section 5037 of this division.

Authority: Section 26013, Business and Professions Code. Reference: Section 26160, Business and Professions Code.

## Chapter 4. MICROBUSINESS

### § 5500. Microbusiness

(a) In order to hold a microbusiness license, a licensee must engage in at least three (3) of the following commercial cannabis activities: cultivation, manufacturing, distribution, and retail sale.

(b) An applicant for a Type 12-Microbusiness license shall indicate on the application for licensure which commercial cannabis activities the applicant intends to engage in.

(c) An application for a Type 12-Microbusiness license shall include:

(1) For an application indicating that the applicant intends to engage in cultivation under the Type 12-Microbusiness license all the required information under sections 5002, 5501, 5502 and 5503 of this division.

(2) For an application indicating that the applicant intends to engage in manufacturing under the Type 12-Microbusiness license all the required information under sections 5002 and 5504 of this division.

(3) For an application indicating that the applicant intends to engage in distribution under the Type 12-Microbusiness license all the required information for an application seeking a Type 11-Distributor license.

(4) For an application indicating that the applicant intends to engage in retail sale under the Type 12-Microbusiness license, all the required information for an application seeking a Type 10-Retailer license.

(d) All cultivation, manufacturing, distribution, and retail activities performed by a licensee under a Type 12-Microbusiness license shall occur on the same licensed premises.

(e) A holder of a Type 12-Microbusiness license shall comply with the following:

(1) A holder of a Type 12-Microbusiness license engaged in cultivation shall comply with all the rules and requirements applicable to the cultivation license type applicable to the cultivation activities of the licensee.

(2) A holder of a Type 12-Microbusiness license engaged in manufacturing shall comply with all the rules and requirements applicable to a Type 6-Manufacturer 1 license.

(3) A holder of a Type 12-Microbusiness license engaged in distribution shall comply with all the rules and requirements applicable to a Type 11-Distributor license.

(4) A holder of a Type 12-Microbusiness license engaged in retail sale shall comply with all the rules and requirements applicable to a Type 10-Retailer license, or a Type 9-Non-Storefront Retailer license if retail sales are conducted by delivery only.

(f) A holder of a Type 12-Microbusiness license may only engage in the commercial cannabis activity requested in the license application and approved by the Bureau at the time the license is issued. If the holder of a Type 12-Microbusiness license wants to engage in an additional

commercial cannabis activity after the license is issued, the licensee shall submit an application to the Bureau indicating the requested changes and providing all information required for an application for the commercial cannabis activity the licensee wants to conduct

(g) A suspension or revocation of a Type 12-Microbusiness licensee shall affect all commercial cannabis activities allowed pursuant to that license.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26013 and 26070, Business and Professions Code.

**§ 5501. Microbusiness Applications Including Cultivation Activities**

In addition to the information required in section 5002 of this division, an application for a microbusiness license to engage in cultivation shall include the following:

(a) Evidence of enrollment with the applicable Regional Water Quality Control Board or State Water Resources Control Board for water quality protection programs or written verification from the appropriate Board that enrollment is not necessary.

(b) Evidence that the applicant has conducted a hazardous materials record search of the EnviroStor database for the proposed premises. If hazardous sites were encountered, the applicant shall provide documentation of protocols implemented to protect employee health and safety.

(c) For indoor and mixed-light cultivation, identification of all power sources for cultivation activities, including, but not limited to: illumination, heating, cooling, and ventilation.

(d) A premises diagram pursuant to section 5006 of this division that shall also include:

(1) All roads and water crossings on the property.

(2) If the applicant is proposing to use a diversion from a waterbody, groundwater well, or rain catchment system as a water source for cultivation, the following locations on the property diagram with locations also provided as coordinates in either latitude and longitude or the California Coordinate System:

(A) Sources of water used, including the location of waterbody diversion(s), pump location(s), and distribution system; and

(B) Location, type, and capacity of each storage unit to be used for cultivation.

(e) A proposed cultivation plan pursuant to section 5502 of this division.

(f) Identification of all water sources used for cultivation activities and the applicable supplemental information for each source as required by section 5503 of this division:

(1) A retail water supplier;

(2) A groundwater well;

(3) A rainwater catchment system; or

(4) A diversion from a surface waterbody or an underground stream flowing in a known and definite channel.

(g) A copy of any final lake or streambed alteration agreement issued by the California Department of Fish and Wildlife, pursuant to sections 1602 and 1617 of the Fish and Game Code, or written verification from the California Department of Fish and Wildlife that a lake and streambed alteration agreement is not required.

(h) An attestation that the applicant entity is an "agricultural employer" as defined by the Alatorre-Zenovich-Dunlap-Berman Agricultural Labor Relations Act of 1975; Part 3.5 (commencing with Section 1140) Division 2 of the Labor Code.

(i) An attestation that the local fire department has been notified of the cultivation site if the applicant entity is an indoor license type.

(j) An acknowledgement that the applicant understands that the information provided in the application that is relevant to the cultivation operation may be shared with the Department of Food and Agriculture for purposes of evaluating the applicant's qualifications for licensure. If the Department of Food and Agriculture corresponds directly with the applicant on matters related to the application, the applicant shall agree to cooperate. The applicant shall further agree that the Department of Food and Agriculture may conduct inspections on the areas of the premises related to their respective oversight authority.

(k) If applicable, a detailed description of any fines or penalties for cultivation or production of a controlled substance on public or private land pursuant to Fish and Game Code section 12025 or 12025.1 against the applicant or a business entity in which the applicant was an owner or officer within 3 years preceding the date of application.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26050, 26051.5 and 26070, Business and Professions Code.

**§ 5502. Cultivation Plan Requirements**

A cultivation plan shall include all of the following:

(a) A detailed premises diagram showing all boundaries and dimensions in feet of the following proposed areas to scale, if applicable:

(1) Canopy area(s) (which shall contain mature plants, at any point in time) including aggregate square footage;

(2) Area(s) outside of the canopy where only immature plants shall be maintained, if applicable;

(3) Designated pesticide and other agricultural chemical storage area(s);

(4) Designated processing area(s) if the licensee will process on site;

(5) Designated packaging area(s) if the licensee will package products on site;

(6) Designated composting area(s) if the licensee will compost plant or cannabis waste on site;

(7) Designated secured area(s) for cannabis waste if different than subsection (a)(6) above;

(8) Designated area(s) for harvested cannabis storage;

(9) Designated research and development area(s) which may contain mature plants for nursery only;

(10) Designated seed production area(s) which may contain mature plants for nursery only; and

(b) For purposes of subsection(a)(1) in this section, canopy shall be calculated in square feet and measured using clearly identifiable boundaries of all areas(s) that will contain mature plants at any point in time, including all of the space(s) within the boundaries. Canopy may be noncontiguous, but each unique area included in the total canopy calculation shall be separated by an identifiable boundary which include, but are not limited to: interior walls, shelves, greenhouse walls, hoop house walls, garden benches, hedgerows, fencing, garden beds, or garden plots. If mature plants are being cultivated using a shelving system, the surface area of each level shall be included in the total canopy calculation.

(c) For indoor and mixed-light cultivation, a lighting diagram with the following information shall be included:

(1) Location of all lights in the canopy area(s); and

(2) Maximum wattage, or wattage equivalent, of each light.

(d) A pest management plan which shall include, but not be limited to, the following:

(1) Product name and active ingredient(s) of all pesticides to be applied to cannabis during any stage of plant growth; and

(2) Integrated pest management protocols including chemical, biological and cultural methods the applicant anticipates using to control or prevent the introduction of pests on the cultivation site.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26050, 26051.5 and 26070, Business and Professions Code.

**§ 5503. Supplemental Water Source Information**

The following information shall be provided for each water source identified by the applicant:

(a) Retail water supply sources:

(1) If the water source is a retail supplier, such as a municipal provider, as defined in Section 13575 of the Water Code, identify the retail water supplier.

(2) If the water source is a small retail supplier, such as a delivery service, and is subject to subdivision (a)(1)(B) of Section 26060.1 of the Business and Professions Code:

(A) And if the contract is for delivery or pickup of water from a surface water body or an underground stream flowing in a known and definite channel, provide all of the following:

(i) The name of the contract water supplier;

(ii) The geographic location coordinates in either latitude and longitude or the California Coordinate System of any point of diversion used by the contract water supplier to divert water delivered to the applicant under the contract;

(iii) The authorized place of use for any water right used by the contract water supplier to divert water delivered to the applicant under the contract; and

(iv) The maximum amount of water delivered to the applicant for cannabis cultivation in any year.

(B) And if the contract is for delivery or pickup of water from a groundwater well, provide all of the following:

(i) The name of the contract water supplier;

(ii) The geographic location coordinates for any groundwater well used to supply water delivered to the applicant, in either latitude and longitude or the California Coordinate System;

(iii) The maximum amount of water delivered to the applicant for cannabis cultivation in any year; and

(iv) A copy of the well log filed with the Department of Water Resources pursuant to Section 13751 of the Water Code for each percolating groundwater well used to divert water delivered to the applicant. If no well log is available, the applicant shall provide evidence from the Department of Water Resources indicating that the Department of Water Resources does not have a record of the well log. When no well log is available, the State Water Resources Control Board may request additional information about the well.

(b) If the water source is a groundwater well:

(1) The groundwater well's geographic location coordinates in either latitude and longitude or the California Coordinate System; and

(2) A copy of the well log filed with the Department of Water Resources pursuant to Section 13751 of the Water Code. If no well log is available, the applicant shall provide evidence from the Department of Water Resources indicating that the Department of Water Resources does not have a record of the well log. If no well log is available, the State Water Resources Control Board may request additional information about the well.

(c) If the water source is a rainwater catchment system:

(1) The total square footage of the catchment footprint area(s);

(2) The total storage capacity, in gallons, of the catchment system(s); and

(3) A detailed description of the type, nature, and location of each catchment surface. Examples of catchment surfaces include a rooftop and greenhouse.

(d) If the water source is a diversion from a waterbody:

(1) Provide any applicable statement, application, permit, license, or small irrigation use registration identification number(s); and either

(A) A copy of any applicable registrations, permits, or licenses or proof of a pending application, issued under Part 2 (commencing with Section 1200) of Division 2 of the Water Code as evidence of approval of a water diversion by the State Water Resources Control Board;

(B) A copy of any statements of diversion and use filed with the State Water Resources Control Board before October 31, 2017, detailing the water diversion and use; or

(C) A copy of documentation submitted to the State Water Resources Control Board before October 31, 2017, demonstrating that the diversion is authorized under a riparian right and that no diversion occurred in any calendar year between January 1, 2010, and January 1, 2017.

(2) If the applicant has claimed an exception from the requirement to file a statement of diversion and use, the applicant shall provide a copy of the documentation submitted to the State Water Resources Control Board before January 1, 2019, demonstrating that the diversion is subject to subdivision (a), (c), (d), or (e) of Section 5101 of the Water Code.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26050, 26051.5 and 26070, Business and Professions Code; and Section 13149, Water Code.

**§ 5504. Microbusiness Applications Including Manufacturing Activities**

In addition to the information required in section 5002 of this division, an application for a microbusiness license that engages or will engage in manufacturing, shall include the following:

(a) Type of manufacturing activity to be conducted at the premises (extraction, infusion, packaging, and/or labeling), and if applicable:

(1) For extraction, the method of non-volatile extraction. If $CO_2$ is used as a method of extraction, a copy of the closed-loop system certification signed by a California-licensed engineer attesting that the system was commercially manufactured, safe for its intended use, and built to codes of recognized and generally accepted good manufacturing practices.

(2) For infusion, a list of all infused products to be manufactured.

(b) A list of all products that will be manufactured, packaged, or labeled, including the following information:

(1) Product type (e.g., edibles) and identity (e.g., brownies);

(2) Product brand name; and

(3) Amount of cannabidiol (CBD) and tetrahydrocannabinol (THC) in the product.

(c) An acknowledgment that the applicant understands that the information provided in the application that is relevant to the manufacturing operation may be shared with the State Department of Public Health for purposes of evaluating the applicant's qualifications for licensure. If the State Department of Public Health corresponds directly with the applicant on matters related to the application, the applicant shall agree to cooperate. The applicant shall

further agree that the State Department of Public Health may conduct inspections on the areas of the premises related to their respective oversight authority.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26050, 26051.5 and 26070, Business and Professions Code.

**§ 5505. Cultivation Records for Licensees Engaging in Cultivation Activities**

(a) Cultivation plan(s);

(b) All records evidencing compliance with the environmental protection measures required in sections 5501, 5502, and 5503 of this chapter;

(c) All lot numbers and batch numbers associated with product in inventory. Lot numbers or batch numbers associated with product that has been retired from the track and trace system must be retained for six (6) months after the date the tags were retired; and

(d) Records associated with the composting or disposal of cannabis waste.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26013, 26069, 26160 and 26161, Business and Professions Code.

**§ 5506 Microbusiness Records for Licensees Engaging in Manufacturing Activities**

(a) In addition to the records required by section 5037 of this division, a microbusiness engaging in manufacturing activities shall maintain batch production records.

(b) The licensee shall prepare a written batch production record every time a batch of cannabis is manufactured. The batch production record shall accurately follow the appropriate manufacturing protocol, and each step of the protocol shall be performed in the production of the batch.

(c) The batch production record shall document complete information relating to the production and control of each batch, including all of the following details:

(1) The batch or lot number of the finished batch of cannabis product of all cannabis products used in the batch;

(2) The identity of equipment and processing lines used in producing the batch;

(3) The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained;

(4) The identification number assigned to each component (or, when applicable, to a cannabis product received from a supplier for packaging or labeling as a cannabis product), packaging, and label used;

(5) The identity and weight or measure of each component used;

(6) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;

(7) The actual results obtained during any monitoring operation;

(8) The results of any testing or examination performed during the batch production, or a cross-reference to such results; and

(9) Documentation, at the time of performance, of the manufacture of the batch, including:

(A) The date on which each step of the manufacturing protocol was performed; and

(B) The initials of the persons performing each step, including:

(i) The initials of the person responsible for weighing or measuring each component used in the batch;

(ii) The initials of the person responsible for verifying the weight or measure of each component used in the batch;

(iii) The initials of the person responsible for adding the component to the batch; and

(iv) The initials of the person responsible for verifying the addition of components to the batch.

(10) Documentation, at the time of performance, of packaging and labeling operations, including:

(A) An actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the manufacturing record;

(B) The expected number of packaging and labels to be used, the actual quantity of the packaging and labels used, and, when label reconciliation is required, reconciliation of any discrepancies between issuance and use of labels; and

(C) The results of any tests or examinations conducted on packaged and labeled cannabis products (including repackaged or relabeled cannabis products), or a cross-reference to the physical location of such results.

(11) Documentation at the time of performance that quality control personnel have:

(A) Reviewed the batch production record;

(B) Reviewed all monitoring operation(s) required in section 40264 of title 17 of the California Code of Regulations;

(C) Reviewed the results of all tests and examinations, including tests and examinations conducted on components, in-process materials, finished batches of cannabis product, and packaged and labeled cannabis products;

(D) Either approved and released--or rejected--the batch for distribution; and

(E) Either approved and released--or rejected-- the finished cannabis product, including any repackaged or relabeled cannabis product.

(12) Documentation at the time of performance of any required material review and disposition decision.

(d) The batch production record shall:

(1) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;

(2) Be accurate, indelible, and legible;

(3) Be created concurrently with performance of the activity documented;

(4) Be as detailed as necessary to provide history of work performed; and:

(A) Include information adequate to identify any associated manufacturing facility (e.g., the name, license number, and when necessary, the location of the facility);

(B) Include the date and, when appropriate, the time of the activity documented;

(C) Include the signature or initials of the person performing the activity; and

(D) Where appropriate, include the identity of the product and the lot number or batch identifier, if any.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26013 and 26160, Business and Professions Code.

## Chapter 5. CANNABIS EVENTS

### § 5600. Cannabis Event Organizer License

(a) To obtain a temporary cannabis event license, the event organizer must first apply for and obtain a cannabis event organizer license.

(b) Cannabis event organizers licensed under this section shall comply with chapter 1 of this division with the exception of sections 5001-5002, 5006-5008, 5010, 5016, 5019, 5025-5029, 5032-5034, and 5042-5055.

(c) A cannabis event organizer licensee is not authorized or licensed to cultivate, distribute, manufacture, or retail cannabis or cannabis products without first obtaining the appropriate licenses or authorizations to engage in such commercial cannabis activities.

(d) A cannabis event organizer shall comply with the records retention provisions of section 5037 of this division. Records shall be kept by the cannabis event organizer in a manner that allows the records to be produced for the Bureau in either hard copy or electronic form, whichever the Bureau requests. Failure to produce records upon the Bureau's request may result in disciplinary action against the cannabis event organizer license and/or denial of a temporary cannabis event license.

(e) Cannabis event organizer applications may be completed online at www.bcc.ca.gov or by delivering a printed copy to the Bureau's office(s).

(f) Applicants who submit their applications online shall first register for a user account as provided by section 5002(b) of this division.

(g) An application must be completed by an owner as defined by Business and Professions Code section 26001(al). An application for cannabis event organizer licensure includes the following:

(1) The name of the applicant. For applicants who are individuals, the applicant shall provide both the first and last name of the individual. For applicants who are business entities, the applicant shall provide the legal business name of the applicant.

(2) If applicable, the business trade name ("DBA") of the applicant.

(3) Whether the owner is serving or has previously served in the military. Disclosure of military service is voluntary. An applicant who has served as an active duty member of the Armed Forces of the United States and was honorably discharged and who can provide evidence of such honorable discharge shall have his or her application expedited pursuant to Business and Professions Code section 115.4.

(4) A list of the license types and the license numbers issued from the Bureau and all other state cannabis licensing authorities that the applicant holds, including the date the license was issued and the licensing authority that issued the license.

(5) Whether the applicant has been denied a license or has had a license suspended or revoked by the Bureau or any other state cannabis licensing authority. The applicant shall provide the type of license applied for, the name of the licensing authority that denied the application, and the date of denial.

(6) The mailing address for the applicant.

(7) The telephone number for the applicant.

(8) The website address of the applicant's business, if applicable.

(9) The email address for the applicant's business.

(10) Contact information for the applicant's designated primary contact person including the name, title, phone number, and email address of the individual.

(11) A description of the business organizational structure of the applicant, such as partnership or corporation.

(12) The business-formation documents, which may include, but are not limited to, articles of incorporation, operating agreements, partnership agreements, and fictitious business name statements. The applicant shall also provide all documents filed with the California Secretary of State, which may include, but are not limited to, articles of incorporation, certificates of stock, articles of organization, certificates of limited partnership, and statements of partnership authority.

(13) A list of every fictitious business name the applicant is operating under including the address where the business is located.

(14) An applicant that is a foreign corporation shall include in its application the certificate of qualification issued by the California Secretary of State under Corporations Code section 2105.

(15) The applicant shall supply the following financial information:

(A) A list of funds belonging to the applicant's cannabis event organizing business held in savings, checking, or other accounts maintained by a financial institution. The applicant shall provide, for each account, the financial institution's name, the financial institution's address, account type, account number, and the amount of money in the account.

(B) A list of loans made to the applicant for its use in cannabis event organizing activities. For each loan, the applicant shall provide the amount of the loan, the date of the loan, term(s) of the loan, security provided for the loan, and the name, address, and phone number of the lender.

(C) A list of investments made into the applicant's cannabis event organizing activities. For each investment, the applicant shall provide the amount of the investment, the date of the investment, term(s) of the investment, and the name, address, and phone number of the investor.

(D) A list of all gifts of any kind given to the applicant for its use in cannabis event organizing activities. For each gift, the applicant shall provide the value of the gift or description of the gift, and the name, address, and phone number of the provider of the gift.

(16) A complete list of every individual that has a financial interest in the cannabis event organizing business as defined in section 5004 of this division, who is not an owner as defined in Business and Professions Code section 26001(al).

(17) A complete list of every owner of the applicant as defined in Business and Professions Code section 26001(al). Each individual named on this list shall submit the following information:

(A) The full name of the owner.

(B) The owner's title within the applicant entity.

(C) The owner's date of birth and place of birth.

(D) The owner's social security number or individual taxpayer identification number.

(E) The owner's mailing address.

(F) The owner's telephone number. This may include a number for the owner's home, business, or mobile telephone.

(G) The owner's email address.

(H) The owner's current employer.

(I) The percentage of the ownership interest held in the applicant entity by the owner.

(J) Whether the owner has an ownership or a financial interest as defined in sections 5003 and 5004, respectively, of this division in any other commercial cannabis business licensed under the Act.

(K) A copy of the owner's government-issued identification. Acceptable forms of identification are a document issued by a federal, state, county, or municipal government that includes the name, date of birth, physical description, and picture of the person, such as a driver license.

(L) A detailed description of the owner's convictions. A conviction within the meaning of this section means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Convictions dismissed under Penal Code section 1203.4 or equivalent non-California law must be disclosed. Convictions dismissed under Health and Safety Code section 11361.8 or equivalent non-California law must be disclosed. Juvenile adjudications and traffic infractions under $300 that did not involve alcohol, dangerous drugs, or controlled substances do not need to be included. For each conviction, the owner shall provide the following:

(i) The date of conviction.

(ii) Dates of incarceration, if applicable.

(iii) Dates of probation, if applicable.

(iv) Dates of parole, if applicable.

(v) A detailed description of the offense for which the owner was convicted.

(vi) A statement of rehabilitation for each conviction. The statement of rehabilitation is to be written by the owner and may contain evidence that the owner would like the Bureau to consider that demonstrates the owner's fitness for licensure. Supporting evidence may be attached to the statement of rehabilitation and may include, but is not limited to, a certificate of rehabilitation under Penal Code section 4852.01, and dated letters of reference from employers, instructors, or professional counselors that contain valid contact information for the individual providing the reference.

(M) If applicable, a detailed description of any suspension of a commercial cannabis license, revocation of a commercial cannabis license, or sanctions for unlicensed commercial cannabis activity by a licensing authority or local agency against the applicant or a business entity in which the applicant was an owner or officer within the three years immediately preceding the date of the application.

(N) Attestation to the following statement: Under penalty of perjury, I hereby declare that the information contained within and submitted with the application is complete, true, and accurate. I understand that a misrepresentation of fact is cause for rejection of this application, denial of the license, or revocation of a license issued.

(18) For an applicant with 20 or more employees, the applicant shall attest that the applicant has entered into a labor peace agreement and will abide by the terms of the agreement, and the applicant shall provide a copy of the agreement to the Bureau. For applicants who have not yet entered into a labor peace agreement, the applicant shall provide a notarized statement indicating the applicant will enter into and abide by the terms of a labor peace agreement.

(19) The limited waiver of sovereign immunity required by section 5009 of this division, if applicable.

Authority: Sections 115.4 and 26013, Business and Professions Code. Reference: Sections 115.4, 144, 26012 and 26200, Business and Professions Code.

**§ 5601. Temporary Cannabis Event License**

(a) A temporary cannabis event license shall only be issued to a person who holds a cannabis event organizer license issued by the Bureau.

(b) Violations of the requirements applicable to temporary cannabis events may result in disciplinary action against the cannabis event organizer license or any other licenses held by a licensee participating in the cannabis event and responsible for the violation under Business and Professions Code section 26070.5.

(c) No temporary cannabis event license will be issued for more than 4 days. Temporary cannabis event licenses will not be issued separately for consecutive days for the same event.

(d) An application for a temporary cannabis event license shall be submitted to the Bureau no less than 60 days before the first day of the cannabis event. An application for a temporary cannabis event license shall include the following:

(1) The name of the applicant. For applicants who are individuals, the applicant shall provide both the first and last name of the individual. For applicants who are business entities, the applicant shall provide the legal business name of the applicant.

(2) The license number for each state cannabis license held by the applicant.

(3) The address of the county fair or district agricultural association where the event will take place.

(4) The name of the event.

(5) A diagram of the physical layout of the event. The diagram shall clearly indicate where the cannabis event will be taking place on the grounds of the event's location, all cannabis consumption areas, all areas where cannabis goods will be sold, and the specific location of each cannabis licensee who will be participating in the event. The diagram shall not contain highlighting and the markings on the diagram shall be in black-and-white print.

(6) The dates for which the temporary cannabis event license is being sought. A temporary event license is required for any date in which the applicant engages in onsite cannabis sales or allows onsite cannabis consumption.

(7) Contact information for the applicant's designated primary contact person regarding the temporary event license, including the name, title, address, phone number, and email address of the individual.

(8) Written approval from the local jurisdiction authorizing the applicant to engage in onsite cannabis sales to, and onsite consumption by, persons 21 years of age or older at the event.

(9) A list of all licensees that will be providing onsite sales of cannabis goods at the event.

(10) Attestation to the following statement: Under penalty of perjury, I hereby declare that the information contained within and submitted with the application is complete, true, and accurate. I understand that a misrepresentation of fact is cause for rejection of this application, denial of the license, or revocation of a license issued.

(e) If the list of licensees participating in the event changes after the application is submitted or after the licensee is issued, the applicant shall submit a final list to the Bureau no less than 5 days before the event. Licensees not on the list may not participate in the event.

Authority: Section 26013, Business and Professions Code. Reference: Section 26200, Business and Professions Code.

**§ 5602. Temporary Cannabis Event Sales**

(a) Prior to selling cannabis goods to a customer, the licensee shall verify that the customer is 21 years of age or older.

(b) Each sale at a cannabis event shall be performed by a retailer or microbusiness authorized to sell cannabis to retail customers. The cannabis event organizer may also sell cannabis goods at the temporary cannabis event if the organizer separately holds a license authorizing the retail sale of cannabis goods.

(c) All sales at a cannabis event shall occur on the dates stated on the license and shall occur at the location stated on the license. All onsite sales of cannabis goods must comply with the requirements of section 5403, subsection (a), of this division.

(d) Sale or consumption of alcohol or tobacco shall not be allowed on the cannabis event premises.

(e) The cannabis goods sold onsite at a cannabis event shall be transported to the site by a distributor.

(f) All cannabis goods at a cannabis event shall be in compliance with all requirements for laboratory testing and labeling within this division.

(g) All cannabis goods at a cannabis event shall be in compliance with all track and trace requirements.

(h) All cannabis goods used for display at a cannabis event shall be in compliance with the requirements of section 5405, subsections (a), (c) and (d), of this division.

(i) All cannabis goods sold at a cannabis event shall be placed in an exit package pursuant to section 5413 of this division.

(j) All customer returns of cannabis goods at a cannabis event shall be made in compliance with section 5410 of this division.

(k) The daily sales limits under section 5409 of this division apply to sales made at a cannabis event.

(l) A retailer shall only provide free cannabis goods to a person at a cannabis event if the retailer complies with all requirements of section 5411 of this division.

(m) The cannabis event organizer who holds the temporary cannabis event license shall be responsible for ensuring that all rules and requirements for the onsite sale of cannabis goods are followed.

Authority: Section 26013, Business and Professions Code. Reference: Section 26200, Business and Professions Code.

**§ 5603. Temporary Cannabis Event Consumption**

(a) Access to the area where cannabis consumption is allowed shall be restricted to persons 21 years of age or older.

(b) The event organizer licensee shall ensure that cannabis consumption is not visible from any public place or non-age-restricted area.

(c) Sale or consumption of alcohol or tobacco shall not be allowed on the premises.

(d) The event organizer shall hire or contract for security personnel to provide security services at the licensed temporary cannabis event. All security personnel hired or contracted for by the licensee shall comply with Chapters 11.4 and 11.5 of Division 3 of the Business and Professions Code.

(e) All requirements for onsite cannabis consumption imposed by the relevant local jurisdiction shall be followed.

(f) The cannabis event organizer, who holds the temporary cannabis event license, shall be responsible for ensuring that all rules and requirements for the onsite consumption of cannabis goods are followed.

(g) A cannabis event organizer and all other licensees participating in a cannabis event are required to follow all applicable requirements in this division pertaining to record keeping and waste management.

(h) Any compensation paid from a retailer to a cannabis event organizer for participation in a cannabis event shall not be determined based on, or tied to, the sale of cannabis goods.

Authority: Section 26013, Business and Professions Code. Reference: Section 26200, Business and Professions Code.

## Chapter 6. TESTING LABORATORIES

### Article 1. Chapter Definitions

### § 5700. Definitions

In addition to the definitions in section 5000 of this division, the following definitions apply to this chapter.

(a) "Acceptance criteria" means the specified limits placed on the characteristics of an item or method that are used to determine data quality.

(b) "Accredited college or university" means a college or university accredited by a regional or national accrediting agency that is an accreditor recognized by the Secretary of the US Department of Education.

(c) "Accreditation body" means an impartial non-profit organization that operates in conformance with the International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) standard 17011 and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for Testing.

(d) "Action level" means the threshold value that provides the criterion for determining whether a sample passes or fails an analytical test.

(e) "Analyte" means a chemical, compound, element, bacteria, yeast, fungus, or toxin to be identified or measured.

(f) "Analytical batch" means a group of samples that is prepared together for the same analysis and analyzed sequentially using the same instrument calibration curve and that have common analytical quality control checks.

(g) "Analytical method" means a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.

(h) "Cannabinoid" means a class of diverse chemical compounds derived from a cannabis plant.

(i) "CAS number" means the unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service, a division of the American Chemical Society.

(j) "CBD" means cannabidiol, CAS number 13956-29-1.

(k) "CBDA" means cannabidiolic acid, CAS number 1244-58-2.

(l) "CBG" means cannabigerol, CAS number 25654-31-3.

(m) "CBN" means cannabinol, CAS number 521-35-7.

(n) "Certificate of accreditation" means a document issued by an accreditation body that attests to the laboratory's competence to carry out specific testing analysis.

(o) "Certificate of analysis" means the report prepared by the laboratory about the analytical testing performed and results obtained by the laboratory.

(p) "Certified reference material" means a reference material prepared by a certifying body or a party independent of the laboratory with ISO/IEC 17034 accreditation.

(q) "Continuing calibration verification" means a type of quality control sample that is a mid-range calibration standard which checks the continued validity of the initial calibration of the instrument.

(r) "Exclusivity" means the specificity of the test method for validating microbial testing methods. It evaluates the ability of the method to distinguish the target organisms from similar but genetically distinct non-target organisms.

(s) "Field duplicate sample" means a sample that is taken in the identical manner and from the same cannabis batch being sampled as the primary sample. It is analyzed separately from the primary sample and is used for quality control purposes only.

(t) "Foreign material" means any filthy, putrid, or decomposed substance including hair, insects, excreta, or related adulterant that may be hazardous or cause illness or injury to the consumer.

(u) "Frequency" means the number of items occurring in each category. Frequency may be determined by analytical method or laboratory specific requirements for accuracy, precision of the analysis, or statistical calculation.

(v) "Sample increment" means a portion of a batch that, together with other increments, makes up the sample.

(w) "Inclusivity" means, related to microbiological method validation, the sensitivity of the test method. It evaluates the ability of the test method to detect a wide range of target organisms by a defined relatedness.

(x) "Inhalable" means consumable in gaseous or vapor form through the lungs.

(y) "ISO/IEC" means the joint technical committee of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

(z) "ISO/IEC 17025" means the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories.

(aa) "ISO/IEC 17034" means the general requirements established by the ISO/IEC for the competence of reference material producers.

(bb) "ISO/IEC 17043" means the general requirements established by the ISO/IEC for proficiency testing.

(cc) "Laboratory" means "testing laboratory" as defined at Business and Professions Code section 26001(as).

(dd) "Laboratory replicate sample" means a duplicate sample of the primary sample used for quality control purposes to demonstrate reproducibility. It is prepared in the identical manner as the primary sample and analyzed separately from the primary sample.

(ee) "Laboratory quality assurance" means the set of operating principles that enable laboratories to produce defensible data of known accuracy and precision and includes employee training, equipment preventative maintenance procedures, calibration procedures, and quality control testing, among other things.

(ff) "Limit of detection" means the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit.

(gg) "Limit of quantitation" means the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision.

(hh) "Matrix" means the substances that are present in a sample except for the analyte(s) of interest.

(ii) "Matrix spike duplicate" means the duplicate sample of the matrix spike sample that is prepared by adding a known quantity of a target analyte to a sample matrix or to a matrix that is as closely representative of the matrix being analyzed as possible.

(jj) "Matrix spike sample" means a sample prepared by adding a known quantity of the target analyte to a sample matrix or to a matrix that is as closely representative of the matrix being analyzed as possible.

(kk) "Method blank" means an analyte free matrix to which all reagents are added in the same volumes or proportions as used in the sample preparation.

(ll) "Moisture content" means the percentage of water in a sample, by weight.

(mm) "Non-target organism" means an organism that the test method or analytical procedure is not testing for and can be used in evaluating the specificity of a test method.

(nn) "Percent recovery" means the percentage of a measured concentration relative to the added (spiked) concentration in a reference material, matrix spike sample, or matrix spike duplicate. A laboratory shall calculate the percent recovery by dividing the sample result by the expected result then multiplying that the quotient by 100.

(oo) "Practical experience" means experience performing scientific analytical tests in a laboratory setting using equipment, instruments, kits, and materials routinely found in a laboratory. Practical experience includes experience in any type of laboratory setting and is not limited to cannabis-specific laboratories.

(pp) "Primary sample" means a sample that is comprised of several increments of either cannabis or cannabis products that are collected from a batch for testing.

(qq) "Proficiency test" means an evaluation of a laboratory's performance against pre-established criteria by means of interlaboratory comparisons of test measurements.

(rr) "Proficiency test sample" means a sample that is prepared by a party independent of the testing laboratory with the ISO/IEC 17043 accreditation, where the concentration and identity of an analyte that is known to the independent party, but is unknown to the testing laboratory and testing laboratory employees.

(ss) "Quality control" means the set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control for which errors have been reduced to acceptable levels.

(tt) "Quality control sample" means a sample that is produced and used by a laboratory for the purpose of assuring the quality of the data and results. Quality control samples include blank samples, matrix spike samples, field duplicate samples, replicate samples, and reference material samples.

(uu) "Reagent" means a compound or mixture added to a system to cause a chemical reaction or test if a reaction occurs. A reagent may be used to tell whether a specific chemical substance is present by causing a reaction to occur with the chemical substance.

(vv) "Reference material" means material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix.

(ww) "Reference method" means the method by which the performance of an alternate method is measured or evaluated.

(xx) "Relative percent difference" means the comparative statistic that is used to calculate precision or random error. RPD is calculated using the following equation:

$$RPD = \left| \text{(primary sample measurement} - \text{duplicate sample measurement)} \right| / \text{([primary sample measurement} + \text{duplicate sample measurement]} / 2) \times 100\%$$

(yy) "Relative standard deviation" means the standard deviation expressed as a percentage of the means recovery. RSD is calculated using the following equation:

$$RSD = (s / x) \times 100\%; \text{ where } s = \text{standard deviation and } x = \text{mean}$$

(zz) "Representative" means a small quantity of the batch whose characteristics represent, as accurately as possible, the entire batch, thus allowing the results to be generalized.

(aaa) "Requester" means the person who submits a request to the laboratory for testing of cannabis or cannabis product from an entity licensed under this division.

(bbb) "Sample" means a representative part of, or a single item from, a batch which is comprised of several sample increments.

(ccc) "Sampler" means the laboratory employee responsible for obtaining samples of cannabis or cannabis product from a distributor.

(ddd) "Sanitize" means to sterilize, disinfect, or make hygienic.

(eee) "Scope of accreditation" means the tests or types of tests performed, materials or products tested, and the methods used for testing cannabis or cannabis products for which the accreditation has been granted.

(fff) "Tamper-evident" means a one-time-use security tape or seal that is affixed to the opening of a package, allowing a person to recognize whether the package has been opened.

(ggg) "Target organism" means an organism that is being tested for in an analytical procedure or test method.

(hhh) "THC" and "delta-9 THC" means tetrahydrocannabinol, CAS number 1972-08-3.

(iii) "THCA" means tetrahydrocannabinolic acid, CAS number 23978-85-0.

(jjj) "Validation" means the confirmation by examination and objective evidence that the requirements for a specific intended use or analytical method are fulfilled.

(kkk) "Water activity" means the measure of the quantity of water in a product that is available and therefore capable of supporting bacteria, yeasts, and fungi and which is reported in units $A_w$.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26013 and 26100, Business and Professions Code.

**Article 2. Laboratory License**

**§ 5701. General Laboratory License Requirements**

(a) A licensed laboratory shall maintain ISO/IEC 17025 accreditation for the testing of the following:

(1) Cannabinoids;

(2) Heavy metals;

(3) Microbial impurities;

(4) Mycotoxins;

(5) Residual pesticides;

(6) Residual solvents and processing chemicals; and

(7) If tested, terpenoids.

(b) A licensed laboratory shall retain, and make available to the Bureau upon request, all records associated with the licensee's ISO/IEC 17025 certificate of accreditation.

Authority: Section 26013, Business and Professions Code. Reference: Section 26100, Business and Professions Code

**§ 5702. Laboratory License Application**

In addition to the information required in section 5002 of this division, an application for a testing laboratory license includes the following:

(a) A valid certificate of accreditation, issued by an accreditation body, that attests to the laboratory's competence to perform testing of the following:

(1) Cannabinoids;

(2) Heavy metals;

(3) Microbial impurities;

(4) Mycotoxins;

(5) Residual pesticides;

(6) Residual solvents and processing chemicals; and

(7) If tested, terpenoids.

(b) Standard operating procedures for the following testing methods:

(1) Cannabinoids;

(2) Foreign material;

(3) Heavy metals;

(4) Microbial impurities;

(5) Moisture content and water activity;

(6) Mycotoxins;

(7) Residual pesticides;

(8) Residual solvents and processing chemicals;

(9) If tested, terpenoids; and

(10) If tested, homogeneity.

(c) Standard operating procedures for the sampling of cannabis and cannabis products.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26012, 26050, 26051.5, 26055, 26102 and 26104, Business and Professions Code.

**§ 5703. Provisional Testing Laboratory License**

(a) A laboratory may apply for a provisional license prior to receiving ISO/IEC 17025 accreditation provided that the applicant meets all other licensure requirements for a testing laboratory and submits to the Bureau an application in compliance with section 5002 of this division and an attestation that the applicant has or intends to seek ISO/IEC 17025 accreditation for all testing methods required by this division.

(b) A provisional testing laboratory license shall be valid for 12 months. The annual license fee for a provisional license shall be determined pursuant to section 5014 of this division.

(c) To timely renew a provisional license, a completed license renewal form and the annual renewal license fee pursuant to section 5014 of this division shall be received by the Bureau from the licensee no earlier than 60 calendar days before the expiration of the license and no later than 5:00 p.m. Pacific Time on the last business day before the expiration of the license if the renewal form is submitted to the Bureau at its office(s), or no later than 11:59 p.m. on the last business day before the expiration of the license if the renewal form is submitted to the Bureau through its electronic licensing system. Failure to receive a notice for license renewal does not relieve a licensee of the obligation to renew a provisional license as required.

(d) In the event the license is not renewed prior to the expiration date, the licensee must not test any commercial cannabis goods until the license is renewed.

(e) A licensee may submit a license renewal form up to 30 days after the license expires. Any late renewal form will be subject to a late fee equal to 50 percent of the applicable licensing fees required by subsection (c) of this section.

(f) The license renewal form shall contain the following:

(1) The name of the licensee. For licensees who are individuals, the applicant shall provide both the first and last name of the individual. For licensees who are business entities, the licensee shall provide the legal business name of the applicant;

(2) The license number and expiration date;

(3) The licensee's address of record and premises address; and

(4) An attestation that all information provided to the Bureau in the original application under section 5002 of this division or subsequent notification under section 5023 of this division is accurate and current.

(g) The Bureau may renew a provisional license for an initial renewal period of 12 months.

(h) After one renewal, the Bureau may renew the provisional license for additional 12-month periods if the licensee has submitted an application for the ISO/IEC 17025 accreditation. In addition to the information required for a renewal form pursuant to subsection (f) of this section, any renewal request pursuant to this section shall also include an attestation that the licensee's application for each ISO/IEC 17025 is pending with the accrediting body, the name of the accrediting body, and the date the application was submitted to the accrediting body.

(i) The licensee shall notify the Bureau if the application for each ISO/IEC 17025 accreditation is granted or denied within 5 business days of receiving the decision from the accrediting body. If the accrediting body grants or denies the licensee's application for any ISO/IEC 17025 accreditation before the expiration of the provisional license, the Bureau may terminate the provisional license at that time.

(j) The Bureau may revoke a provisional license at any time.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26012 and 26050, Business and Professions Code.

**Article 3. Sampling Cannabis and Cannabis Products**

**§ 5704. Sampling Standard Operating Procedures**

(a) The laboratory shall develop and implement a sampling standard operating procedure (SOP) that describes the laboratory's method for obtaining representative samples of cannabis and cannabis product.

(b) The sampling SOP shall include the following information:

(1) A procedure for obtaining samples of each matrix type the laboratory samples, and

(2) A procedure for the collection of samples to perform homogeneity analysis of edible cannabis products.

(c) The sampling SOP shall specify that during sampling, the sampler shall, at minimum:

(1) Follow the laboratory's sampling SOP;

(2) Ensure that the sampling area is free of contaminants;

(3) Sanitize sampling tools between each batch;

(4) Use disposable gloves and change gloves between each batch;

(5) Weigh samples to within 0.1 gram of accuracy using a calibrated balance;

(6) Collect both a primary and a field duplicate sample from each batch;

(7) Place the sample in a container capable of preventing degradation or contamination and seal the sample container with tamper-evident material;

(8) Assign a unique sample identifier to both the primary and field duplicate samples;

(9) Record on the sample field log the conditions under which the sample is transported and stored;

(10) Follow chain of custody protocols; and

(11) Complete the sample field log.

(d) The supervisory or management laboratory employee shall review, approve, sign, and date the sampling SOP and each revision thereto.

(e) The laboratory shall retain a copy of the sampling SOP on the laboratory premises and ensure that the sampling SOP is accessible to the sampler during sampling.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26102, 26104 and 26110, Business and Professions Code.

**§ 5705. General Sampling Requirements**

(a) The laboratory that obtains samples from a distributor shall perform the required testing.

(b) The laboratory may obtain and analyze samples only from batches in final form as required by Business and Professions Code section 26100.

(c) The laboratory shall collect both a primary sample and a field duplicate sample from each batch. The primary sample and field duplicate sample shall be stored and analyzed separately.

(d) The laboratory shall ensure that the sample is transported and subsequently stored at the laboratory in a manner that prevents degradation, contamination, and tampering. If the cannabis or cannabis product specifies on the label how the product shall be stored, the laboratory shall store the sample as indicated on the label.

(e) The laboratory shall complete a chain of custody form and sample field log for each sample that the laboratory collects and analyzes.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5706. Sample Field Log**

The sampler shall use a sample field log to record the following information for each sampled batch:

(a) Laboratory's name, address, and license number;

(b) Sampler's name(s) and title(s);

(c) Date and time sampling started and ended;

(d) Distributor's name, address, and license number;

(e) Cultivator's, manufacturer's, or microbusiness' name, address, and license number;

(f) Batch number of the batch from which the sample was obtained;

(g) Sample matrix;

(h) Total batch size, by weight or unit count;

(i) Total weight or unit count of the primary sample;

(j) Total weight or unit count of the field duplicate sample;

(k) The unique sample identification number for each sample; and

(l) Sampling conditions or problems encountered during the sampling process, if any.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5707. Harvest Batch Sampling**

(a) The sampler shall obtain both a primary sample and a field duplicate sample from each prepacked or unpacked harvest batch. The primary sample and field duplicate sample must each weigh 0.35% of the total harvest batch weight. The sampler shall collect the field duplicate sample contemporaneous to, and in the same manner as, collection of the primary sample.

(b) A sampler may collect greater than 0.35% of a prepacked or unpacked harvest batch per primary sample and field duplicate sample if necessary to perform the required testing or to ensure that the samples obtained are representative.

(c) The prepacked or unpacked harvest batch from which a sample is obtained shall weigh no more than 50.0 pounds. Laboratory analyses of a sample collected from a harvest batch weighing more than 50.0 pounds shall be deemed invalid and the harvest batch from which the sample was obtained may not be released for retail sale.

(d) When the sampler obtains a primary sample and a field duplicate sample from an unpacked harvest batch, the sampler shall do all the following:

(1) Collect the number of increments per primary sample and field duplicate sample relative to the unpacked harvest batch size as listed in the following table;

(2) Obtain increments from random and varying locations of the unpacked harvest batch, both vertically and horizontally. To the extent practicable, the increments obtained from an unpacked harvest batch shall be of equal weight; and

(3) To the extent practicable, collect an equal number of increments from each container if the unpacked harvest batch is stored in multiple containers.

| **Unpacked Harvest Batch Size (pounds)** | **Number of Increments (per sample)** |
|---|---|
| ≤ 10.0 | 8 |
| 10.1 – 20.0 | 16 |
| 20.1 – 30.0 | 23 |
| 30.1 – 40.0 | 29 |
| 40.1 – 50.0 | 34 |

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5708. Cannabis Product Batch Sampling**

(a) The sampler shall collect both a primary sample and a field duplicate sample from each cannabis product batch. The sampler shall collect the field duplicate sample contemporaneous to, and in the same manner as, collection of the primary sample.

(b) The sampler may collect a greater number of increments per primary sample and field duplicate sample if necessary to perform the required testing or to ensure that the samples obtained are representative.

(c) The cannabis product batch from which a primary sample and a field duplicate sample are obtained shall contain no more than 150,000 units. Laboratory analyses of a sample collected from a cannabis product batch containing more than 150,000 units shall be deemed invalid and the cannabis product batch from which the primary sample and a field duplicate sample were obtained may not be released for retail sale.

(d) The sampler shall obtain a primary sample and a field duplicate sample of cannabis product by collecting, at minimum, the number of increments per sample relative to the cannabis product batch size as listed in the following table. Each increment consists of 1 packaged unit.

| Cannabis Product Batch Size (units) | Number of Increments (per sample) |
|---|---|
| ≤ 50 | 2 |
| 51 – 150 | 3 |
| 151 – 500 | 5 |
| 501 – 1,200 | 8 |
| 1,201 – 3,200 | 13 |
| 3,201 – 10,000 | 20 |
| 10,001 – 35,000 | 32 |
| 35,001 – 150,000 | 50 |

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5709. Chain of Custody (COC) Protocol**

(a) The laboratory shall develop and implement a COC protocol to ensure accurate documentation of the transport, handling, storage, and destruction of samples.

(b) The COC protocol shall require the use of a COC form that contains, at minimum, the following information:

(1) Laboratory's name, physical address, and license number;

(2) Distributor's name, physical address, and license number;

(3) Unique sample identifier;

(4) Date and time of the sample collection;

(5) Printed and signed name(s) of the distributor(s);

(6) Printed and signed name(s) of the sampler(s); and

(7) Printed and signed name(s) of the testing laboratory employee who received the sample.

(c) Each time the sample changes custody between licensees, is transported, or is destroyed, the date, time, and the names and signatures of persons involved in these activities shall be recorded on the COC form.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5710. Laboratory Receipt of Samples Obtained from a Distributor**

(a) The laboratory may accept and analyze a sample from a distributor for the required testing under section 5714 of this division only if there is an accompanying COC form for the sample.

(b) The laboratory shall not analyze a sample obtained from a distributor, and the batch from which the sample was obtained may not be released for retail sale, if the any of the following occur:

(1) The sample is received at the laboratory without the requisite COC form;

(2) The tamper-evident material is broken prior to the sample being received at the laboratory; or

(3) There is evidence of sample commingling, contamination, degradation, or a related occurrence rendering the sample unusable for analytical testing when the sample is received at the laboratory.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**Article 4. Standard Operating Procedures**

**§ 5711. Laboratory Analyses Standard Operating Procedures**

(a) The laboratory shall develop, implement, and maintain written standard operating procedures (SOP) for the following laboratory processes:

(1) Sample preparation. Sample preparation SOP(s) shall address the following:

(A) Sample homogenization;

(B) Handling and storage;

(C) Preservation; and

(D) Hold time.

(2) Test methods. Each test method SOP shall address the following:

(A) Test method name;

(B) Applicable analytes and matrices;

(C) Method sensitivity;

(D) Potential interferences with the analysis, if any;

(E) Analytical instruments used for testing;

(F) Types, frequency, and acceptance criteria for quality control samples;

(G) Types, frequency, and acceptance criteria for calibration standards;

(H) Procedure for analyzing analytical batch samples;

(I) Calculation of results, if any; and

(J) Reagent, solution, standards, and reference material preparation, if any.

(b) The supervisory or management laboratory employee shall review, approve, sign, and date each SOP and each revision thereto.

(c) The laboratory shall keep each SOP at the laboratory premises and ensure that each SOP is accessible to laboratory employees during operating hours.

(d) The laboratory shall make each SOP available for inspection by the Bureau upon request, as well as any other SOPs associated with the licensee's ISO/IEC 17025 certificate of accreditation.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26102, 26104 and 26110, Business and Professions Code.

**§ 5712. Test Methods**

(a) The laboratory shall develop, implement, and validate test methods for the analyses of samples as required under this division.

(b) To the extent practicable, the laboratory test methods shall comport with the following guidelines:

(1) US Food and Drug Administration's *Bacterial Analytical Manual*, 2016;

(2) AOAC International's *Official Methods of Analysis for Contaminant Testing of AOAC International*, 20th Edition, 2016; and

(3) United States Pharmacopeia and the National Formulary's *Methods of Analysis for Contaminant Testing*, 2016.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5713. Validation of Test Methods**

(a) The laboratory may use a nonstandard, amplified, or modified test method or a method that is designed or developed by the laboratory to validate the methods for analyses of samples.

(b) The laboratory shall follow the guidelines set forth in the US Food and Drug Administration's *Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds*, 2nd Edition, 2015, incorporated herein by reference, to validate test methods for the microbial analysis.

(1) The laboratory shall include and address the criteria listed in the following table when validating test methods for microbial analyses of samples.

| Criteria | Requirement |
|---|---|
| Number of target organisms; inclusivity | 5 |
| Number of non-target organisms; exclusivity | 5 |
| Number of analyte levels per matrix: Qualitative methods | 3 levels: high and low inoculum levels and 1 uninoculated level |
| Number of analyte levels per matrix: Quantitative methods | 4 levels: low, medium and high inoculum levels and 1 uninoculated level |
| Replicates per food at each level tested | 2 or more replicates per level |

(c) The laboratory shall follow the guidelines set forth in the US Food and Drug Administration's *Guidelines for the Validation of Chemical Methods for the FDA FVM Program*, 2nd Edition, 2015, incorporated herein by reference, to validate test methods for chemical analysis of samples.

(1) The laboratory shall include and address the following criteria to validate test methods for chemical analyses of samples:

(A) Accuracy;

(B) Precision;

(C) Linearity and range;

(D) Calibration standard;

(E) Sensitivity and selectivity;

(F) Limit of detection and limit of quantitation;

(G) Recovery;

(H) Reproducibility; and

(I) Robustness.

(d) If available, the laboratory shall use cannabis reference materials or certified reference materials to validate test methods.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**Article 5. Laboratory Testing and Reporting**

**§ 5714. Required Testing**

(a) The laboratory shall test each sample for the following:

(1) Cannabinoids;

(2) Foreign material;

(3) Heavy metals;

(4) Microbial impurities;

(5) Mycotoxins;

(6) Moisture content and water activity;

(7) Residual pesticides;

(8) Residual solvents and processing chemicals;

(9) If applicable, terpenoids; and

(10) If applicable, homogeneity.

(b) The laboratory shall report the results of each analysis performed by the laboratory on the certificate of analysis.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5715. Phase-In of Required Laboratory Testing**

(a) Cannabis and cannabis products shall not be sold or transferred to a retailer, or released for retail sale, unless a representative sample of the cannabis or cannabis product has undergone and passed all testing as required by this section.

(b) All cannabis harvested on or after January 1, 2018, and all cannabis products manufactured on or after January 1, 2018, shall be tested for the following analytes, if applicable:

(1) Cannabinoids as required in section 5724 of this division;

(2) Moisture content as required in section 5717 of this division;

(3) Category II Residual Solvents and Processing Chemicals as required in section 5718 of this division;

(4) Category I Residual Pesticides as required in section 5719 of this division;

(5) Microbial Impurities as required in section 5720 of this division; and

(6) Homogeneity as required in section 5716 of this division.

(c) In addition to the requirements of subsection (b) of this section, all cannabis harvested on or after July 1, 2018, and all cannabis products manufactured on or after July 1, 2018, shall be tested for the following analytes, if applicable:

(1) Category I Residual Solvents and Processing Chemicals as required in section 5718 of this division;

(2) Category II Residual Pesticides as required in section 5719 of this division; and

(3) Foreign Material as required in section 5722 of this division.

(d) In addition to the requirements in subsections (b) and (c) of this section, all cannabis harvested on or after December 31, 2018, and all cannabis products manufactured on or after December 31, 2018, shall be tested for the following analytes, if applicable:

(1) Terpenoids as required in section 5725 of this division;

(2) Mycotoxins as required in section 5721 of this division;

(3) Heavy Metals as required in section 5723 of this division; and

(4) Water Activity as required in section 5717 of this division.

(e) Licensees may have a sample of cannabis or cannabis products tested for analytes that are not yet required to be tested. However, if the sample fails any additional test(s) not required pursuant to this section on the date of testing, the batch from which the sample was collected fails testing and shall not be released for retail sale.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100 and 26104, Business and Professions Code.

**§ 5716. Homogeneity Testing of Edible Cannabis Products**

(a) The laboratory shall analyze a sample of edible cannabis product that contains more than one serving per unit to determine whether the edible cannabis product is of homogeneous THC content.

(b) The laboratory shall perform homogeneity testing when the first batch of edible cannabis product is tested before entering the retail market. Once the initial batch of the product passes homogeneity testing, and provided that the process for manufacturing and the composition of the edible cannabis product remains the same, a batch of edible cannabis product shall be tested for homogeneity every 6 months thereafter.

(c) A sample of edible cannabis product shall be deemed to have passed homogeneity testing if the relative standard deviation of THC concentration between the samples collected does not exceed plus or minus 10%.

(d) If a sample fails homogeneity testing, or the laboratory fails to perform homogeneity testing as required by this section, the batch from which the sample was collected fails homogeneity testing and may not be released for retail sale.

(e) If a sample passes homogeneity testing, the laboratory shall perform all other analyses required under this chapter.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5717. Moisture Content and Water Activity Testing**

(a) The laboratory shall analyze a sample of cannabis to determine the level of water activity and the percentage of moisture content.

(b) A cannabis sample shall be deemed to have passed water activity testing if the water activity does not exceed 0.65 $A_w$. The laboratory shall report the result of the water activity test on the certificate of analysis (COA) and indicate "pass" or "fail" on the COA.

(c) A cannabis sample shall be deemed to have passed moisture content testing if the moisture content does not exceed 13.0%. The laboratory shall report the result of the moisture content test in percentage on the COA and indicate "pass" or "fail" on the COA.

(d) The laboratory shall analyze edible cannabis products to determine the level of water activity. A solid or semi-solid edible cannabis product shall be deemed to have passed water activity testing if the water activity does not exceed 0.85 $A_w$. The laboratory shall report the result of the water activity test on the COA and indicate "pass" or "fail" on the COA.

(e) If a sample fails moisture content testing, the batch from which the sample was collected fails moisture content testing and shall not be released for retail sale.

(f) If a sample fails water activity testing, the batch from which the sample was collected fails water activity testing and shall not be released for retail sale.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5718. Residual Solvents and Processing Chemicals Testing**

(a) The laboratory shall analyze a sample of cannabis product to determine whether residual solvents or processing chemicals are present.

(b) The laboratory shall report the result of the residual solvents and processing chemicals testing in unit micrograms per gram (µg/g) on the COA and indicate "pass" or "fail" on the COA.

(c) A sample shall be deemed to have passed the residual solvents and processing chemicals testing if both of the following conditions are met:

(1) The presence of any residual solvent or processing chemical listed in the following tables in Category I is not detected, and

(2) The presence of any residual solvent or processing chemical listed in the following tables in Category II does not exceed the indicated action levels.

| **Category I Residual Solvent or Processing Chemical** | **CAS No.** |
|---|---|
| 1,2-Dichloroethane | 107-06-2 |
| Benzene | 71-43-2 |
| Chloroform | 67-66-3 |
| Ethylene oxide | 75-21-8 |
| Methylene chloride | 62-73-7 |
| Trichloroethylene | 79-01-6 |

| Category II Residual Solvent or Processing Chemical | CAS No. | Action Level (µg/g) | |
|---|---|---|---|
| | | Inhalable Cannabis and Cannabis Products | Other Cannabis and Cannabis Products |
| Acetone | 67-64-1 | 3100 | 5000 |
| Acetonitrile | 75-05-8 | 6 | 410 |
| Butane | 106-97-8 | 5000 | 5000 |
| Ethanol | 64-17-5 | 5000 | 5000 |
| Ethyl acetate | 141-78-6 | 5000 | 5000 |
| Ethyl ether | 60-29-7 | 5000 | 5000 |
| Heptane | 142-82-5 | 5000 | 5000 |
| Hexane | 110-54-3 | 70 | 290 |
| Isopropyl alcohol | 67-63-0 | 320 | 5000 |
| Methanol | 67-56-1 | 400 | 3000 |
| Pentane | 109-66-0 | 5000 | 5000 |
| Propane | 74-98-6 | 5000 | 5000 |
| Toluene | 108-88-3 | 30 | 890 |
| Total xylenes (ortho-, meta-, para-) | 1330-20-7 | 10 | 2170 |

(d) If a sample fails residual solvents and processing chemicals testing, the batch from which the sample was collected fails residual solvents and processing chemicals testing and shall not be released for retail sale.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5719. Residual Pesticides Testing**

(a) The laboratory shall analyze a sample of cannabis or cannabis product to determine whether residual pesticides are present.

(b) The laboratory shall report the result of the residual pesticides testing in unit micrograms per gram (µg/g) on the COA and indicate "pass" or "fail" on the COA.

(c) A sample shall be deemed to have passed the residual pesticides testing if both of the following conditions are met:

(1) The presence of any residual pesticide listed in the following tables in Category I are not detected, and

(2) The presence of any residual pesticide listed in the following tables in Category II does not exceed the indicated action levels.

| **Category I Residual Pesticide** | **CAS No.** |
|---|---|
| Aldicarb | 116-06-3 |
| Carbofuran | 1563-66-2 |
| Chlordane | 57-74-9 |
| Chlorfenapyr | 122453-73-0 |
| Chlorpyrifos | 2921-88-2 |
| Coumaphos | 56-72-4 |
| Daminozide | 1596-84-5 |
| DDVP (Dichlorvos) | 62-73-7 |
| Dimethoate | 60-51-5 |
| Ethoprop(hos) | 131947-48-4 |
| Etofenprox | 80844-07-1 |
| Fenoxycarb | 72490-01-8 |
| Fipronil | 120068-37-3 |
| Imazalil | 35554-44-0 |
| Methiocarb | 2032-65-7 |
| Methyl parathion | 298-00-0 |
| Mevinphos | 7786-34-7 |
| Paclobutrazol | 76738-62-0 |
| Propoxur | 114-26-1 |
| Spiroxamine | 118134-30-8 |
| Thiacloprid | 111988-49-9 |

| Category II Residual Pesticide | CAS No. | Action Level (µg/g) | |
|---|---|---|---|
| | | Inhalable Cannabis and Cannabis Products | Other Cannabis and Cannabis Products |
| Abamectin | 71751-41-2 | 0.1 | 0.3 |
| Acephate | 30560-19-1 | 0.1 | 5 |
| Acequinocyl | 57960-19-7 | 0.1 | 4 |
| Acetamiprid | 135410-20-7 | 0.1 | 5 |
| Azoxystrobin | 131860-33-8 | 0.1 | 40 |
| Bifenazate | 149877-41-8 | 0.1 | 5 |
| Bifenthrin | 82657-04-3 | 3 | 0.5 |
| Boscalid | 188425-85-6 | 0.1 | 10 |
| Captan | 133-06-2 | 0.7 | 5 |
| Carbaryl | 63-25-2 | 0.5 | 0.5 |
| Chlorantraniliprole | 500008-45-7 | 10 | 40 |
| Clofentezine | 74115-24-5 | 0.1 | 0.5 |
| Cyfluthrin | 68359-37-5 | 2 | 1 |
| Cypermethrin | 52315-07-8 | 1 | 1 |
| Diazinon | 333-41-5 | 0.1 | 0.2 |
| Dimethomorph | 110488-70-5 | 2 | 20 |
| Etoxazole | 153233-91-1 | 0.1 | 1.5 |
| Fenhexamid | 126833-17-8 | 0.1 | 10 |
| Fenpyroximate | 111812-58-9 | 0.1 | 2 |
| Flonicamid | 158062-67-0 | 0.1 | 2 |
| Fludioxonil | 131341-86-1 | 0.1 | 30 |
| Hexythiazox | 78587-05-0 | 0.1 | 2 |
| Imidacloprid | 138261-41-3 | 5 | 3 |
| Kresoxim-methyl | 143390-89-0 | 0.1 | 1 |

| Category II Residual Pesticide | CAS No. | Action Level (µg/g) | |
|---|---|---|---|
| | | Inhalable Cannabis and Cannabis Products | Other Cannabis and Cannabis Products |
| Metalaxyl | 57837-19-1 | 2 | 15 |
| Methomyl | 16752-77-5 | 1 | 0.1 |
| Myclobutanil | 88671-89-0 | 0.1 | 9 |
| Naled | 300-76-5 | 0.1 | 0.5 |
| Oxamyl | 23135-22-0 | 0.5 | 0.2 |
| Pentachloronitrobenzene | 82-68-8 | 0.1 | 0.2 |
| Permethrin | 52645-53-1 | 0.5 | 20 |
| Phosmet | 732-11-6 | 0.1 | 0.2 |
| Piperonylbutoxide | 51-03-6 | 3 | 8 |
| Prallethrin | 23031-36-9 | 0.1 | 0.4 |
| Propiconazole | 60207-90-1 | 0.1 | 20 |
| Pyrethrins | 8003-34-7 | 0.5 | 1 |
| Pyridaben | 96489-71-3 | 0.1 | 3 |
| Spinetoram | 187166-15-0, 187166-40-1 | 0.1 | 3 |
| Spinosad | 131929-60-7, 131929-63-0 | 0.1 | 3 |
| Spiromesifen | 283594-90-1 | 0.1 | 12 |
| Spirotetramat | 203313-25-1 | 0.1 | 13 |
| Tebuconazole | 107534-96-3 | 0.1 | 2 |
| Thiamethoxam | 153719-23-4 | 5 | 4.5 |
| Trifloxystrobin | 141517-21-7 | 0.1 | 30 |

(d) If a sample fails residual pesticides testing, the batch from which the sample was collected fails pesticides testing and shall not be released for retail sale.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5720. Microbial Impurities Testing**

(a) The laboratory shall analyze a sample of cannabis or cannabis product to determine whether microbial impurities are present.

(b) The laboratory shall report the result of the microbial impurities testing by indicating "pass" or "fail" on the COA.

(c) A sample of inhalable cannabis or inhalable cannabis product shall be deemed to have passed the microbial impurities testing if all of the following conditions are met:

(1) Shiga toxin–producing *Escherichia coli* is not detected in 1 gram;

(2) *Salmonella* spp. is not detected in 1 gram; and

(3) Pathogenic *Aspergillus* species *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus* are not detected in 1 gram.

(d) A sample of other cannabis or cannabis product shall be deemed to have passed the microbial impurities testing if both the following:

(1) Shiga toxin–producing *Escherichia coli* is not detected in 1 gram, and

(2) *Salmonella* spp. is not detected in 1 gram.

(e) If a sample fails microbial impurities testing, the batch from which the sample was collected fails microbial impurities testing and shall not be released for retail sale.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5721. Mycotoxin Testing**

(a) The laboratory shall analyze a sample of cannabis or cannabis product to determine whether mycotoxins are present.

(b) The laboratory shall report the result of the mycotoxins testing in unit micrograms per kilograms (µg/kg) on the COA and indicate "pass" or "fail" on the COA.

(c) A sample shall be deemed to have passed mycotoxin testing if both the following conditions are met:

(1) Total of aflatoxin B1, B2, G1, and G2 does not exceed 20 µg/kg of substance, and

(2) Ochratoxin A does not exceed 20 µg/kg of substance.

(d) If a sample fails mycotoxin testing, the batch from which the sample was collected fails mycotoxin testing and shall not be released for retail sale.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5722. Foreign Material Testing**

(a) The laboratory shall analyze a sample of cannabis or cannabis product to determine whether foreign material is present.

(b) The laboratory shall report the result of the foreign material test by indicating "pass" or "fail" on the COA.

(c) The laboratory shall perform foreign material testing on the total primary sample prior to sample homogenization.

(d) When the laboratory performs foreign material testing, at minimum, the laboratory shall do all of the following:

(1) Examine both the exterior and interior of the cannabis sample, and

(2) Examine the exterior of the cannabis product sample.

(e) A sample shall be deemed to have passed the foreign material testing if the presence of foreign material does not exceed:

(1) 1/4 of the total sample area covered by sand, soil, cinders, or dirt;

(2) 1/4 of the total sample area covered by mold;

(3) 1 insect fragment, 1 rodent hair, or 1 count mammalian excreta per 3.0 grams; or

(4) 1/4 of the total sample area covered by an imbedded foreign material.

(f) If a sample fails foreign material testing, the batch from which the sample was collected fails foreign material testing and shall not be released for retail sale.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5723. Heavy Metals Testing**

(a) The laboratory shall analyze a sample of cannabis or cannabis product to determine whether heavy metals are present.

(b) The laboratory shall report the result of the heavy metals test in micrograms per gram (µg/g) on the COA and indicate "pass" or "fail" on the COA.

(c) A sample shall be deemed to have passed the heavy metals testing if the presence of heavy metals does not exceed the action levels listed in the following table.

(d) If a sample fails heavy metals testing, the batch from which the sample was collected fails heavy metals testing and shall not be released for retail sale.

| Heavy Metal | Action Level (µg/g) | |
|---|---|---|
| | Inhalable Cannabis and Cannabis Products | Other Cannabis and Cannabis Products |
| Cadmium | 0.2 | 0.5 |
| Lead | 0.5 | 0.5 |
| Arsenic | 0.2 | 1.5 |
| Mercury | 0.1 | 3.0 |

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5724. Cannabinoid Testing**

(a) The laboratory shall analyze a sample of cannabis or cannabis product to determine whether the cannabinoid profile of the sample conforms to the labeled content of each cannabinoid such as THC; THCA; CBD; CBDA; CBG; and CBN.

(b) The laboratory shall report the result of the cannabinoid testing on the COA both as a percentage and in milligrams per gram (mg/g) dry-weight using the following equation and indicate "pass" or "fail" on the COA:

Dry-weight percent cannabinoid = wet-weight percent cannabinoid / (1 – percent moisture / 100)

(c) If the labeled content of any one cannabinoid is expressed as a total concentration of the cannabinoid, the laboratory shall calculate the total cannabinoid concentration as follows:

Total cannabinoid concentration (mg/g) = (cannabinoid acid form concentration (mg/g) x 0.877) + cannabinoid concentration (mg/g)

(d) A sample shall be deemed to have passed the cannabinoid testing if the concentration of any one cannabinoid does not exceed the labeled content of the cannabinoid, plus or minus 10%.

(e) If the sample fails cannabinoid testing, the batch from which the sample was collected fails cannabinoid testing and shall not be released for retail sale.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5725. Terpenoid Testing**

(a) The laboratory shall analyze a sample of cannabis or cannabis product to determine whether the terpenoid profile of the sample conforms to the labeled content of terpenoids.

(b) The laboratory shall report the result of the terpenoid testing on the COA both as a percentage and in milligrams per gram (mg/g) and indicate "pass" or "fail" on the COA.

(c) A sample shall be deemed to have passed the terpenoid testing if the concentration of terpenoids does not exceed the labeled content of total terpenoids, plus or minus 10 percent.

(d) If a sample fails terpenoid testing, the batch from which the sample was collected fails terpenoid testing and shall not be released for retail sale.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5726. Certificate of Analysis (COA)**

(a) The laboratory shall generate a COA only for each primary sample that the laboratory analyzes.

(b) The laboratory shall, within 1 business day of completing analyses of a sample, both enter the COA information into the track and trace system and provide a copy of the COA to the requester.

(c) The COA shall contain, at minimum, the following information:

(1) Laboratory's name, address, and license number;

(2) Distributor's name, address, and license number;

(3) Cultivator's, manufacturer's, or microbusiness' name, address, and license number;

(4) Batch number of the batch from which the sample was obtained;

(5) Sample identifying information, including matrix type and unique sample identifiers;

(6) Sample history, including the date collected, the date received by the laboratory, and the date(s) of sample analyses and corresponding testing results;

(7) For cannabis samples, the total weight, in grams, of both the primary sample and the total batch size;

(8) For cannabis product samples, the total unit count of both the primary sample and the total batch size;

(9) The identity of the analytical methods used and corresponding Limits of Detection (LOD) and Limits of Quantitation (LOQ); and

(10) Analytes detected during the analyses of the sample that are unknown, unidentified, or injurious to human health if consumed, if any.

(d) The laboratory shall report test results for each primary sample on the COA as follows:

(1) When reporting quantitative results for each analyte, the laboratory shall use the appropriate units of measurement as required under this chapter;

(2) When reporting qualitative results for each analyte, the laboratory shall indicate "pass" or "fail";

(3) When reporting results for each test method, the laboratory shall indicate "pass" or "fail";

(4) When reporting results for any analytes that were detected below the analytical method LOQ, indicate "<LOQ";

(5) When reporting results for any analytes that were not detected or detected below the LOD, indicate "ND"; and

(6) Indicate "NT" for any test that the laboratory did not perform.

(e) The laboratory supervisory or management employee shall validate the accuracy of the information contained on the COA and sign and date the COA.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**Article 6. Post Testing Procedures**

**§ 5727. Remediation and Retesting**

(a) A harvest batch or cannabis product batch that has been additionally processed after a failed testing must be retested and successfully pass all the analyses required under this chapter.

(b) A harvest batch or cannabis product batch that failed testing because of nonconformance with the labeled content may be relabeled so that the batch conforms with the labeled content.

(c) A harvest batch or cannabis product batch may only be remediated twice. If the batch fails after the second remediation attempt and the second retesting, the entire batch shall not be released for retail sale.

(d) Within 1 business day of completing the required analyses of a sample obtained from a remediated harvest batch or remediated cannabis product batch, the laboratory shall enter the COA information into the track and trace system.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5728. Post Testing Sample Retention**

(a) The laboratory shall retain the reserve sample, consisting of any portion of a sample that was not used in the testing process. The reserve sample shall be kept, at minimum, for 45 business days after the analyses, after which time it may be destroyed and denatured to the point the material is rendered unrecognizable.

(b) The laboratory shall securely store the reserve sample in a manner that prohibits sample degradation, contamination, and tampering.

(c) The laboratory shall provide the reserve sample to the Bureau upon request.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**Article 7. Laboratory Quality Assurance and Quality Control**

**§ 5729. Laboratory Quality Assurance (LQA) Program**

(a) The laboratory shall develop and implement a LQA program to assure the reliability and validity of the analytical data produced by the laboratory. The LQA program shall, at minimum, include a written LQA manual that addresses the following:

(1) Quality control procedures;

(2) Laboratory organization and employee training and responsibilities;

(3) LQA objectives for measurement data;

(4) Traceability of data and analytical results;

(5) Instrument maintenance, calibration procedures, and frequency;

(6) Performance and system audits;

(7) Steps to change processes when necessary;

(8) Record retention;

(9) Test procedure standardization; and

(10) Method validation.

(b) The supervisory or management laboratory employee shall annually review, amend if necessary, and approve the LQA program and manual both when they are created and when there is a change in methods, laboratory equipment, or the supervisory or management laboratory employee.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5730. Laboratory Quality Control (LQC) Samples**

(a) The laboratory shall use LQC samples in the performance of each analysis according to the following specifications.

(b) The laboratory shall analyze LQC samples in the same manner as the laboratory analyzes cannabis and cannabis product samples.

(c) The laboratory shall use negative and positive controls for microbial testing.

(d) The laboratory shall prepare and analyze at least one LQC sample for each analytical batch within each set of 20 samples for the following LQC samples:

(1) Method blank;

(2) Continuing calibration verification (CCV);

(3) Laboratory replicate sample; and

(4) Matrix spike sample or matrix spike duplicate sample.

(e) If the result of the analyses is outside the specified acceptance criteria in the following table, the laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

| **Laboratory Quality Control Sample** | **Acceptance Criteria** |
|---|---|
| Method blank sample for chemical analysis | Not to exceed LOQ |
| Reference material and certified reference material for chemical analysis | Percent recovery 80% - 120% |
| Laboratory replicate sample | RPD no greater than 20% |
| Matrix spike or matrix spike duplicate sample for chemical analysis | Percent recovery between 80% to 120% |
| CCV for chemical analysis | Percent recovery between 80% to 120% |
| Cannabis product field duplicate sample | RPD no greater than 20% |
| Cannabis field duplicate sample | RPD no greater than 30% |

(f) The laboratory shall generate a LQC sample report for each analytical batch that includes LQC parameters, measurements, analysis date, and matrix.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5731. Limits of Detection (LOD) and Limits of Quantitation (LOQ) for Quantitative Analyses**

(a) The laboratory shall calculate the LOD for chemical method analyses according to any of the following methods:

(1) Signal-to-noise ratio of between 3:1 and 2:1;

(2) Standard deviation of the response and the slope of calibration curve using a minimum of 7 blank samples; or

(3) A method published by the United States Food and Drug Administration (USFDA) or the United States Environmental Protection Agency (USEPA).

(b) The laboratory shall calculate the LOQ for chemical method analyses according to any of the following methods:

(1) Signal-to-noise ratio of 10:1, at minimum;

(2) Standard deviation of the response and the slope using a minimum of 7 blank samples calculated as follows:

LOQ = (10 × standard deviation of the response) / slope of the calibration curve; or

(3) A method published by the USFDA or the USEPA.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104 and 26110, Business and Professions Code.

**§ 5732. Data Package**

(a) The laboratory shall generate a data package for each batch of samples that the laboratory analyzes. At a minimum, the data package shall contain the following:

(1) The name and address of the laboratory that performed the analytical procedures;

(2) The names, functions, and signatures of the laboratory employees that performed the sample preparation, analyses, and reviewed and approved the data;

(3) All batch sample results and batch LQC sample results;

(4) Raw data, including instrument raw data, for each sample, if any;

(5) Instrument test method with parameters, if any;

(6) Instrument tune report, if any;

(7) Instrument calibration data, if any;

(8) LQC sample report with worksheets, forms, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis;

(9) Analytical batch sample sequence, if any;

(10) The field sample log and the COC form; and

(11) The COA created as required under this chapter.

(b) After the data package is compiled, the supervisory or management laboratory employee shall do the following:

(1) Review the analytical results for technical correctness and completeness;

(2) Verify that the results of each analysis carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively; and

(3) Approve the laboratory results by signing and dating the data package prior to release of the data by the laboratory.

(c) The data package shall be kept for a minimum of 7 years and shall be made available upon request by the Bureau.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100, 26104, 26110 and 26160, Business and Professions Code.

**§ 5733. Required Proficiency Testing**

(a) The laboratory shall participate in a proficiency testing program ("PT program") provided by an organization that operates in conformance with the requirements of ISO/IEC 17043, at least once every six months after receiving ISO/IEC 17025 accreditation.

(b) The laboratory shall participate in the PT program by following the laboratory's existing SOPs for testing cannabis and cannabis products.

(c) The laboratory shall rotate the PT program among the analytical methods in the laboratory's scope of accreditation and among the employees who perform the test methods.

(d) Laboratory employees who participate in a PT program shall sign the corresponding analytical reports or attestation statements to certify that the PT program was conducted in the same manner as the laboratory tests of cannabis and cannabis products.

(e) A supervisory or management laboratory employee shall review and verify the accuracy of results reported for all PT program samples analyzed.

(f) The laboratory shall provide PT program results to the Bureau within 3 business days after the laboratory receives notification of their test results from the PT program provider.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100 and 26110, Business and Professions Code.

**§ 5734. Satisfactory and Unsatisfactory Proficiency Test Performance**

(a) The laboratory shall be deemed to have successfully participated in a PT program for an analyte tested in a specific method if the test results demonstrate a "satisfactory" or otherwise proficient performance determination by the PT program provider.

(b) The laboratory may not report test results for analytes that are deemed by the PT program provider as "unacceptable," "questionable," "unsatisfactory", or otherwise deficient.

(c) The laboratory may resume reporting test results for analytes that were deemed "unacceptable," "questionable," "unsatisfactory", or otherwise deficient, only if both of the following conditions are met:

(1) The laboratory satisfactorily remedies the cause of the failure for each analyte; and

(2) The laboratory submits, to the Bureau, a written report demonstrating how the laboratory has fixed the cause of the failure.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100 and 26110, Business and Professions Code.

**§ 5735. Internal audit**

(a) The laboratory shall conduct an internal audit at least once per year or in accordance with the ISO/IEC 17025 accrediting body's requirement, whichever is more frequent.

(b) The internal audit must include all of the components required by the ISO/IEC 17025 internal-audit standards.

(c) Within 3 business days of completing the internal audit, the laboratory shall submit the results of the internal audit to the Bureau.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26100 and 26104, Business and Professions Code.

**Article 8. Employee Qualifications**

**§ 5736. General Employee Qualifications**

(a) The laboratory may only employ persons who are at least 21 years of age.

(b) The laboratory shall develop and implement an employee training program to ensure competency of employees for their assigned functions.

(c) The laboratory shall ensure and document that each employee meets the employee qualifications.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26102 and 26104, Business and Professions Code.

**§ 5737. Supervisor or Management Responsibilities and Qualifications**

(a) The laboratory shall employ a supervisor or management employee who must be responsible for:

(1) Overseeing and directing the scientific methods of the laboratory;

(2) Ensuring that the laboratory achieves and maintains a laboratory quality assurance program as required by section 5729 of this division; and

(3) Providing ongoing and appropriate training to laboratory employees.

(b) To be considered qualified, the supervisor or management employee must have earned, at minimum:

(1) A doctoral degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university;

(2) A master's degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university, plus at least 2 years of full-time practical experience; or

(3) A bachelor's degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university, plus at least 4 years of full-time practical experience.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26102 and 26104, Business and Professions Code.

**§ 5738. Analyst and Sampler Qualifications**

(a) The laboratory shall employ an analyst who, at minimum, must have either:

(1) Earned a master's degree or a bachelor's degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university; or

(2) Completed 2 years of college or university education that included coursework in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university, plus at least 3 years of full-time practical experience.

(b) The laboratory shall employ a sampler who, at minimum, must have either:

(1) Completed 2 years college or university education; or

(2) Earned a High School Diploma or passed a General Educational Development or High School Equivalency exam, plus at least 1 year of full-time practical experience.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26102 and 26104, Business and Professions Code.

**Article 9. Record Retention**

**§ 5739. Records**

All testing laboratory-specific records described in this chapter shall be maintained in accordance with section 5037 of this division.

Authority: Section 26013, Business and Professions Code. Reference: Section 26160, Business and Professions Code.

**Chapter 7. ENFORCEMENT**

**§ 5800. Right of Access**

(a) The Bureau, and its authorized representatives, shall have full access to inspect and:

(1) Enter onto any premises licensed by the Bureau.

(2) Test any vehicle or equipment possessed by, in control of, or used by a licensee or their agents and employees for the purpose of conducting commercial cannabis activity.

(3) Test any cannabis goods or cannabis-related materials or products possessed by, in control of, or used by a licensee or their agents and employees for the purpose of conducting commercial cannabis activity.

(4) Copy any materials, books, or records of any licensee or their agents and employees.

(b) Failure to cooperate with and participate in any Bureau investigation pending against the licensee may result in a licensing violation subject to discipline. This subsection shall not be construed to deprive a licensee of any privilege guaranteed by the Fifth Amendment to the Constitution of the United States, or any other constitutional or statutory privileges. This subsection shall not be construed to require a licensee to cooperate with a request that would require the licensee to waive any constitutional or statutory privilege or to comply with a request for information or other matters within an unreasonable period of time in light of the time constraints of the licensee's business. Any constitutional or statutory privilege exercised by the licensee shall not be used against the licensee in a regulatory or disciplinary proceeding against the licensee.

(c) The Bureau, and its authorized representatives, shall have the rights of access under subsection (a), during any inspection, investigation, review, or audit, or as otherwise allowed by law.

(d) Prior notice of an inspection, investigation, review, or audit is not required.

(e) Any inspection, investigation, review, or audit of a licensed premises shall be conducted anytime the licensee is exercising privileges under the license, or as otherwise agreed to by the Bureau and the licensee or its agents, employees, or representatives.

Authority: Section 26013, Business and Professions Code; Reference: Sections 26012 and 26015, Business and Professions Code.

**§ 5801. Notice to Comply**

(a) The Bureau may issue a notice to comply to a licensee for violation(s) of the Act or regulations observed during an inspection.

(b) The notice to comply shall be in writing and describe the nature and facts of each violation, including a reference to the statute or regulation violated, and may indicate the manner in which the licensee must correct the violation(s) to achieve compliance.

(c) The Bureau will serve the notice to comply prior to leaving the licensed premises after the inspection on any licensee, employee, agent, or person delegated by any of the aforementioned persons, to facilitate the inspection or accept such notice, or will mail the notice to comply within 15 calendar days of the last date of inspection.

(d) The notice to comply shall inform the licensee that the licensee may, within 15 calendar days from the date of personal service or mailing of the notice to comply, sign and return the notice to comply declaring under penalty of perjury that each violation was corrected and describing how compliance was achieved.

(e) Failure to correct the violation(s) in the notice to comply may result in a disciplinary action.

Authority: Section 26013, Business and Professions Code; Reference: Sections 26012 and 26018, Business and Professions Code.

**§ 5802. Citations; Orders of Abatement; Administrative Fines**

(a) The Bureau may issue citations containing orders of abatement and fines against a licensee, or an unlicensed person, for any acts or omissions which are in violation of any provision of the Act or any regulation adopted pursuant thereto.

(b) The Bureau may issue a citation under this section to a licensee for a violation of a term or condition contained in a decision placing that licensee on probation.

(c) Each citation:

(1) Shall be in writing.

(2) Shall describe with particularity the nature of the violation, including a reference to the law or regulation determined to have been violated.

(3) May contain an assessment of an administrative fine of up to $5,000, and/or an order of abatement fixing a reasonable time for abatement of the violation;

(4) Shall be served personally or by certified mail; and

(5) Shall inform the licensee or person that he or she may request an informal conference, or contest the citation, or both, pursuant to section 5803.

(d) Failure to pay a fine within 30 calendar days of the date of assessment, unless the citation is being contested, may result in further action being taken by the Bureau including, but not limited to, suspension or revocation of a license. If a citation is not appealed and the fine is not paid, the full amount of the assessed fine shall be added to the fee for renewal of the license. A license shall not be renewed without the payment of the renewal fee and fine.

(e) The amount of any fine to be levied by the Bureau shall take into consideration the factors listed in subdivision (b)(3) of Section 125.9 of the Business and Professions Code.

(f) Nothing in this section shall be deemed to prevent the Bureau from filing an accusation to suspend or revoke a license where grounds for such suspension or revocation exist.

Authority: Sections 125.9 and 26013, Business and Professions Code. Reference: Sections 125.9, 148, 149 and 26012, Business and Professions Code.

**§ 5803. Contesting Citations**

(a) A cited licensee or person may, within 30 calendar days of service of the citation, contest the citation by requesting a hearing in writing to the Bureau or such hearing is waived. The hearing shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code.

(b) In addition to requesting a hearing provided for in subsection (a) of this section, the cited licensee or person may, within 15 calendar days after service of the citation, submit a written request for an informal conference with the Bureau regarding the acts or omissions charged in the citation.

(c) The Bureau shall, within 15 calendar days from receipt of the written request, hold an informal conference with the licensee or person cited, and/or his or her legal counsel or authorized representative.

(d) At the conclusion of the informal conference, the Bureau may affirm, modify, or dismiss the citation, including any fines levied or orders of abatement issued. A written decision stating the reasons for the decision shall be mailed to the cited licensee or person and his or her legal counsel, if any, within 15 calendar days from the date of the informal conference. This decision shall be deemed to be a final order with regard to the citation issued, including the levied fine and the order of abatement, if any.

(e) If the citation is dismissed, any request for a hearing shall be deemed withdrawn. If the citation is affirmed or modified, the cited licensee or person may, in his or her discretion, withdraw the request for a hearing or proceed with the administrative hearing process.

(f) If the citation, including any fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 calendar days in accordance with subdivision (b)(4) of section 125.9 of the Business and Professions Code.

Authority: Section 26013, Business and Professions Code. Reference: Sections 125.9, 26012 and 26016, Business and Professions Code.

**§ 5804. Citation Compliance**

(a) The time to abate or correct a violation as provided for in an order of abatement may be extended for good cause. If a cited licensee or person who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond his or her control after the exercise of reasonable diligence, the licensee or person cited may request an extension of time from the Bureau in which to complete the correction. Such a request shall be in writing and shall be made within the time set forth for abatement.

(b) When a citation is not contested, or if it is appealed and the person cited does not prevail, failure to abate the violation within the time allowed or pay a fine that was imposed shall constitute a violation and a failure to comply with the citation or order of abatement.

(c) Failure to timely comply with an order of abatement or pay a fine that was imposed may result in further action being taken by the Bureau, including, but not limited to, suspension or revocation of a license, or further administrative or civil proceedings.

Authority: Section 26013, Business and Professions Code. Reference: Sections 125.9 and 26012, Business and Professions Code.

**§ 5805. Minor Decoys**

(a) Peace officers may use a person under 21 years of age to attempt to purchase cannabis goods, for the purposes of enforcing the Act, and to apprehend licensees, employees, or agents of licensees who sell cannabis goods to minors. For purposes of this section, a "minor" is a person under 21 years of age.

(b) The following minimum standards shall apply to the use of a minor decoy:

(1) At the time of the operation, the decoy shall be less than 20 years of age.

(2) A decoy shall either carry his or her own identification showing the decoy's correct date of birth, or carry no identification. A decoy who carries identification shall present it upon request to any seller of cannabis goods.

(3) A decoy shall answer truthfully any questions about his or her age.

(4) Following any completed sale, but not later than the time a citation, if any, is issued, the peace officer directing the decoy shall make a reasonable attempt to enter the licensed premises or respond to the location where the licensee is located and have the minor decoy who purchased cannabis goods identify the alleged seller of the cannabis goods.

Authority: Sections 26013 and 26140, Business and Professions Code. Reference: Section 26140, Business and Professions Code.

**§ 5806. Attire and Conduct**

(a) No license shall allow the following:

(1) Employment or use of any person in the sale or service of cannabis goods in or upon the licensed premises while such person is unclothed or in such attire, costume, or clothing as to expose to view any portion of the male or female breast below the top of the areola or of any portion of the pubic hair, anus, cleft of the buttocks, vulva, or genitals.

(2) Employment or use of the services of any host or other person to mingle with the patrons while such hostess or other person is unclothed or in such attire, costume, or clothing as described in subsection (a)(1) of this section.

(3) Encouraging or permitting any person on the licensed premises to touch, caress, or fondle the breasts, buttocks, anus, or genitals of any other person.

(4) Permitting any employee or person to wear or use any device or covering, exposed to view, which simulates the breast, genitals, anus, pubic hair, or any portion thereof.

Authority: Section 26013, Business and Professions Code. Reference: 26011.5, Business and Professions Code.

**§ 5807. Entertainers and Conduct**

(a) Live entertainment is permitted on a licensed premises, except that:

(1) No licensee shall permit any person to perform acts of or acts that simulate:

(A) Sexual intercourse, masturbation, sodomy, bestiality, oral copulation, flagellation, or any sexual acts that are prohibited by law.

(B) Touching, caressing, or fondling of the breast, buttocks, anus, or genitals.

(C) Displaying of the buttocks, breasts, pubic hair, anus, vulva, or genitals.

(b) No licensee shall permit any person to use artificial devices or inanimate objects to depict any of the prohibited activities described above.

(c) No licensee shall permit any person to remain in or upon the licensed premises who exposes to public view any portion of his or her breast, buttocks, genitals, or anus.

Authority: Section 26013, Business and Professions Code. Reference: 26011.5, Business and Professions Code.

**§ 5808. Additional Grounds for Discipline**

The following include, but are not limited to, additional grounds that constitute a basis for disciplinary action:

(a) Failure to take reasonable steps to correct objectionable conditions on the licensed premises, including the immediately adjacent area that is owned, leased, or rented by the licensee, that constitute a nuisance, within a reasonable time after receipt of notice to make those corrections, under Section 373a of the Penal Code.

(b) Failure to take reasonable steps to correct objectionable conditions that occur during operating hours on any public sidewalk abutting a licensed premises and constitute a nuisance, within a reasonable time after receipt of notice to correct those conditions from the Bureau. This subsection shall apply to a licensee only upon written notice to the licensee from the Bureau. The Bureau shall issue this written notice upon its own determination, or upon a request from the local law enforcement agency in whose jurisdiction the premises is located, that is supported by substantial evidence that persistent objectionable conditions are occurring on the public sidewalk abutting the licensed premises. For purposes of this subsection:

(1) "Any public sidewalk abutting a licensed premises" means the publicly owned, pedestrian-traveled way, not more than 20 feet from the premises, that is located between a licensed premises, including any immediately adjacent area that is owned, leased, or rented by the licensee, and a public street.

(2) "Objectionable conditions that constitute a nuisance" means disturbance of the peace, public intoxication, drinking alcoholic beverages in public, smoking or ingesting cannabis or cannabis products in public, harassment of passersby, gambling, prostitution, loitering, public urination, lewd conduct, drug trafficking, or excessive loud noise.

(3) "Reasonable steps" means all of the following:

(A) Calling the local law enforcement agency. Timely calls to the local law enforcement agency that are placed by the licensee, or his or her agents or employees, shall not be construed by the Bureau as evidence of objectionable conditions that constitute a nuisance.

(B) Requesting those persons engaging in activities causing objectionable conditions to cease those activities, unless the licensee, or his or her agents or employees, feel that their personal safety would be threatened in making that request.

(C) Making good faith efforts to remove items that facilitate loitering, such as furniture, except those structures approved or permitted by the local jurisdiction. The licensee shall not be liable for the removal of those items that facilitate loitering.

(4) When determining what constitutes "reasonable steps," the Bureau shall consider site configuration constraints related to the unique circumstances of the nature of the business.

(c) Notwithstanding that the licensee corrects the objectionable conditions that constitute a nuisance, the licensee has a continuing obligation to meet the requirements of subsections (a) and (b), and failure to do so shall constitute grounds for disciplinary action.

(d) If a licensee has knowingly permitted the illegal sale, or negotiations for the sales, of controlled substances or dangerous drugs upon his or her licensed premises. Successive sales, or negotiations for sales, over any continuous period of time shall be deemed evidence of permission. As used in this section, "controlled substances" shall have the same meaning as is given that term in Article 1 (commencing with Section 11000) of Chapter 1 of Division 10 of the Health and Safety Code, and "dangerous drugs" shall have the same meaning as is given that term in Article 2 (commencing with Section 4015) of Chapter 9 of Division 2 of the Business and Professions Code.

(e) If the licensee has employed or permitted any persons to solicit or encourage others, directly or indirectly, to buy such persons cannabis goods in the licensed premises under any commission, percentage, salary, or other profit-sharing plan, scheme, or conspiracy.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26011.5 and 26030, Business and Professions Code.

**§ 5809. Disciplinary Actions**

(a) When an accusation recommending disciplinary action against a license has been filed pursuant to Section 26031 of the Business and Professions Code, the accusation shall be served on the licensee in accordance with Section 11505 of the Government Code.

(b) A hearing shall be conducted in accordance with the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code to determine if cause exists to take action against the licensee. At such a hearing, the Bureau shall have all the powers granted therein and by the Business and Professions Code.

(c) If a hearing on an accusation against a licensee results in a finding that the licensee has committed any of the acts or omissions constituting grounds for disciplinary action, the Bureau may order the license revoked, suspended outright for a specified period of time, or suspended on probationary restriction for a specified period of time on such terms and conditions of probation as in its judgment are supported by its findings, impose a fine, or any combination thereof. The Bureau may also issue such other lawful orders it considers to be appropriate on the basis of its findings.

(d) An accusation may be terminated by written stipulation at any time prior to the conclusion of the hearing on the accusation. If a licensee submits a proposed stipulation to the Bureau for its consideration and the Bureau subsequently declines to accept the proposed stipulation, the Bureau shall not thereafter be disqualified from hearing evidence on the accusation and taking action thereon as authorized in this section.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26012, 26031 and 26034, Business and Professions Code.

**§ 5810. Interim Suspension**

(a) Pursuant to Business and Professions Code section 494, the Bureau may petition for an interim order to suspend any license or impose licensing restrictions upon any licensee, if:

(1) The licensee has engaged in acts or omissions constituting a violation of the Business and Professions Code or this division, or been convicted of a crime substantially related to the licensed activity, and

(2) Permitting the licensee to continue to engage in the licensed activity would endanger the public health, safety, or welfare.

(b) An interim order for suspension or restrictions may issue with notice, as follows:

(1) The Bureau shall provide the licensee with at least 15 days' notice of the hearing on the petition for an interim order.

(2) The notice shall include documents submitted in support of the petition.

(c) An interim order for suspension or restrictions may issue without notice to the licensee, as follows:

(1) If it appears from the Bureau's petition and supporting documents that serious injury would result to the public before the matter could be heard on notice.

(2) The Bureau shall provide the licensee with a hearing on the petition within 20 days after issuance of the initial interim order.

(3) Notice of the hearing shall be provided within two days after issuance of the initial interim order.

(d) The Bureau shall file an accusation, pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, within 15 calendar days of the issuance of the interim order.

Authority: Section 26013, Business and Professions Code; Reference: Sections 494, 26011.5, 26012 and 26031, Business and Professions Code.

**§ 5811. Posting of Notice of Suspension**

(a) A licensee whose license has been suspended shall conspicuously and continuously display a notice on the exterior of the licensee's premises for the duration of the suspension.

(b) The notice shall be two feet in length and 14 inches in width. The notice shall read:

NOTICE OF SUSPENSION
The Bureau of Cannabis Control License(s)
Issued For This Premises Has Been Suspended
For Violation of State Law

(c) Advertising or posting signs to the effect that the premises have been closed or that business has been suspended for any reason other than the reason provided in the decision suspending the license, shall be deemed a violation of this section.

(d) Failure to display the notice as required in this section or removal of the notice prior to the expiration of the suspension shall be a violation of this section and may result in additional disciplinary action.

(e) A licensee shall notify the Bureau within 24 hours of discovering that the notice under subsection (b) of this section has been removed or damaged to an extent that makes the notice illegible.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26011.5 and 26012, Business and Professions Code.

**§ 5812. Posting of Notice of Revocation**

(a) A licensee whose license has been revoked shall conspicuously display a notice on the exterior of the licensee's premises indicating that the license has been revoked. The notice shall remain continuously on the licensed premises for at least 15 calendar days.

(b) The notice shall be two feet in length and 14 inches in width. The notice shall read:

NOTICE OF REVOCATION
The Bureau of Cannabis Control License(s)
Issued For This Premises Has Been Revoked
For Violation of State Law

(c) Advertising or posting signs to the effect that the premises have been closed or that business has been suspended for any reason other than the reason provided in the decision revoking the license shall be deemed a violation of this section.

(d) If the Bureau revokes a license at a licensed premises that has one or more licenses at the location that will remain active after the revocation, the revocation notice shall remain posted for a period of at least 15 calendar days.

(e) Failure to display for the time required in this section shall be a violation of this section and may result in additional disciplinary action.

(f) A licensee shall notify the Bureau within 24 hours of discovering that the notice under subsection (b) of this section has been removed or damaged to an extent that makes the notice illegible.

Authority: Section 26013, Business and Professions Code. Reference: Sections 26011.5 and 26012, Business and Professions Code.

**§ 5813. Enforcement Costs**

(a) In any order in resolution of a disciplinary proceeding for suspension or revocation of a license, the Bureau may request the administrative law judge to direct a licensee found to have committed a violation or violations of the Act, or any regulation adopted pursuant to the Act, to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

(b) A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the Bureau's designated representative shall be prima facie evidence of reasonable costs of investigation and prosecution of the case. The costs shall include the amount of investigative and enforcement costs up to the date of the hearing, including, but not limited to, charges imposed by the Attorney General.

(c) The administrative law judge shall make a proposed finding of the amount of reasonable costs of investigation and prosecution of the case when requested pursuant to subsection (a). The Bureau may reduce or eliminate the cost award, or remand to the administrative law judge where the proposed decision fails to make a finding on costs requested pursuant to subsection (a).

(d) Where an order for recovery of costs is made and timely payment is not made as directed in the decision, the Bureau may enforce the order for repayment in any appropriate court. This right of enforcement shall be in addition to any other rights the Bureau may have as to any licensee to pay costs.

(e) In any action for recovery of costs, proof of the decision shall be conclusive proof of the validity of the order of payment and the terms for payment.

(f) Except as provided in subsection (g) of this section, the Bureau shall not renew or reinstate any license of any licensee who has failed to pay all of the costs ordered under this division.

(g) Notwithstanding subsection (f) of this section, the Bureau may, in its discretion, conditionally renew or reinstate for a maximum of one year the license of any licensee who demonstrates financial hardship and who enters into a formal agreement with the Bureau for reimbursement within that one-year period for the unpaid costs.

(h) Nothing in this section shall preclude the Bureau from including the recovery of the costs of investigation and enforcement of a case in any stipulated settlement.

Authority: Section 26013, Business and Professions Code; Reference: Sections 125.3 and 26031, Business and Professions Code

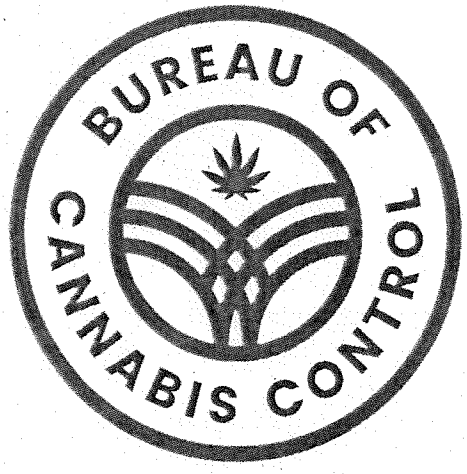
**§ 5814. Disciplinary Guidelines**

In reaching a decision on a disciplinary action under the Act and the Administrative Procedures Act (Govt. Code section 11400 et seq.), the Bureau shall consider the disciplinary guidelines entitled "Bureau of Cannabis Control Disciplinary Guidelines November 2017," which are hereby incorporated by reference. Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the Bureau in its sole discretion determines that the facts of the particular case warrant such a deviation, e.g., the presence of mitigating factors, the age of the case, or evidentiary problems.

Authority: Section 26013, Business and Professions Code; Reference: Section 26031, Business and Professions Code.

# BUREAU OF CANNABIS CONTROL

# DISCIPLINARY GUIDELINES




## NOVEMBER 2017

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# I. INTRODUCTION

Pursuant to Business and Professions Code section 26011.5, the protection of the public is of the highest priority for the Bureau of Cannabis Control (Bureau). In keeping with its mandate to protect the public, the Bureau has adopted these recommended uniform guidelines in order to promote consistency in disciplinary orders for similar offenses on a statewide basis. This document is intended for use by those involved in the administrative disciplinary process (e.g., Administrative Law Judges (ALJ), Deputy Attorneys General (DAG), Bureau licensees and their legal counsel, and other interested parties), and may be revised from time to time, and distributed to interested parties upon request.

The Bureau requests that the suggested disciplinary orders contained in these guidelines be levied consistently and appropriately, based on the nature and seriousness of the violation(s) confirmed in an administrative action. The Bureau recognizes that mitigating or aggravating circumstances, in addition to other factors, may necessitate departure from these recommended orders and terms of probation. If there are any deviations from the guidelines, the Bureau requests that the ALJ hearing the matter include an explanation in the Proposed Decision so that the circumstances can be better understood and evaluated by the Bureau before final action is taken.

Additionally, these guidelines only apply to formal administrative disciplinary processes. These guidelines do not apply to other alternatives available to the Bureau, such as administrative citations and fines, except in cases where an Accusation has been filed against a registrant or licensee for failure to pay an assessed administrative fine and/or comply with an order of abatement issued by the Bureau.

## II. FACTORS TO BE CONSIDERED IN DETERMINING PENALTIES

In determining whether revocation, suspension, probation, fine, or a combination is to be imposed in a given case, factors such as the following should be considered:

1. Nature and severity of the act(s), offenses, or crime(s) under consideration.
2. Actual or potential harm to the public.
3. Actual or potential harm to any patient.
4. Prior disciplinary record.
5. Number and/or variety of current violations.
6. Mitigating evidence.
7. Rehabilitation evidence, including but not limited to, a statement of rehabilitation containing any evidence that demonstrates fitness for licensure, or a certificate of rehabilitation under Penal Code section 4852.01.
8. In case of a criminal conviction, compliance with conditions of sentence and/or court-ordered probation.
9. Overall criminal record.
10. Time passed since the act(s) or offense(s) occurred.
11. If applicable, evidence of expungement proceedings pursuant to Penal Code Section 1203.4.

## III. DISCIPLINARY GUIDELINES

The Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) specifies the offenses for which the Bureau may take disciplinary action. Following are samples of the codes and regulation numbers, titles of the offenses and the associated Bureau determined disciplinary recommendations. When filing an accusation, the Bureau or Office of the Attorney General are not limited to the violations listed herein. They may also cite any and all additional related statutes and regulations violated not listed below. The following is ***not*** a comprehensive list of potential violations and in no way, should limit the Bureau or the Attorney General's Office from asserting any relevant and applicable violation. The Bureau suggests that for cases with multiple violations, suspensions or other disciplines run concurrently. All standard terms of probation as stated herein shall be included for all probations.

As used herein, statutes and regulations are referenced as follows:
Business and Professions Code: (B&P)
Title 16, California Code of Regulations: (CCR)
Penal Code: (PC)

**California Code of Regulations Disciplinary Order Guidelines - Tier 1**

**Minimum:** revocation stayed, 5 to 15-day suspension, a fine (as determined by the "Fine Formula" below), or a combination of a suspension and fine.

**Maximum:** revocation

Tier 1 discipline is recommended for:

- violations which are potentially harmful

Violations of the following codes are representative of this category:

| Violation Description | Authority |
|---|---|
| Failure to Surrender License | B&P § 119 (d)<br>CCR § 5022 |
| Failure to Notify the Bureau of Changes | CCR § 5023 |
| Unauthorized Modification of Licensed Premises | B&P § 26055(c)<br>CCR § 5027 |
| Prohibited Commercial Cannabis Activity Between Medicinal and Adult-Use Licensees | CCR § 5032(b) |
| Unauthorized Storage of Inventory | CCR § 5033 |
| Failure to Maintain Records | B&P § 26160<br>CCR §§ 5037(a), 5310, 5426, 5505-5506 |
| Allowing the Unauthorized Use of the Track and Trace System and Failing to Maintain Track and Trace System Requirements | CCR §§ 5048-5050 and 5052 |
| Failure to Properly Display and Post License | CCR § 5039 |

| | |
|---|---|
| Failure to Comply with Advertising and Marketing Requirements | B&P §§ 26151- 26152<br>CCR §§ 5040-5041 |
| Failure to Ensure Restricted Access to Limited-Access and Other Restricted Areas | B&P § 26070<br>CCR §§ 5042 and 5401 |
| Failure to Comply with Security Requirements | CCR §§ 5043-5047 and 5403(b)(1)-(2) |
| Failure to Comply with Proper Cannabis Destruction and Waste Management | CCR §§ 5054-5055 and 5410(e) |
| Unauthorized Storage of Cannabis Goods and Storage-only Services | CCR §§ 5033 and 5300-5302 |
| Failure to Comply with Packaging and Labeling Requirements | B&P § 26070<br>CCR §§ 5303 and 5412 |
| Failure to Comply with Insurance Requirements | CCR § 5308 |
| Failure to Comply with Inventory Documentation and Reconciliation Requirements | CCR §§ 5051, 5309 and 5423-5424 |
| Failure to Comply with Transportation Requirements of Cannabis Goods | B&P § 26070<br>CCR §§ 5311-5312 |
| Failure to Comply with Transport Personnel Requirements | CCR § 5313 |
| Unauthorized Use of Distributor Transport Only License | CCR § 5315 |
| Failure to Comply with Shipping Manifest Requirements | B&P §§ 26067 and 26070<br>CCR § 5314 |
| Unauthorized Hours of Operation | CCR § 5403(a) and (b)(3), and 5422(b) |
| Unauthorized Sale of Cannabis Plants | CCR § 5408(a)-(b) |
| Use of Pesticide on Live Plants | CCR § 5408(c) |
| Unauthorized Furnishing of Free Cannabis Goods | CCR § 5411 |
| Failure to Comply with Exit Packaging Requirements | B&P § 26070.1<br>CCR § 5413 |
| Failure to Comply with Delivery Requirements | CCR §§ 5415-5418 and 5421 |
| Failure to Provide Delivery Request Receipts | B&P § 26090<br>CCR § 5420 |
| Unauthorized Receipt of Inventory Shipment | CCR § 5422 |
| Failure to Record Sales to Customer | CCR § 5425 |
| Failure to Comply with Requirements for Temporary Cannabis Event License | CCR § 5600 et seq. |
| Non-Permitted Use of License | B&P § 119(b)-(f) |
| Failure to Comply with Local Ordinance Regulating Commercial Cannabis Activity | B&P § 26030(f) |
| Failure to Comply with Operating Procedures | B&P § 26030(j) |
| Sale of Alcohol or Tobacco Products | B&P § 26054(a) |
| Failure to Record Commercial Cannabis Activity on Sales Invoice or Receipt | B&P § 26161 |
| Failure to Exercise Care for Safety of Self or Others Due to Being Under the Influence of an Intoxicating Substance | PC § 647(f) |

## California Code of Regulations Disciplinary Order Guidelines - Tier 2

**Minimum:** revocation stayed, 15 to 30-day suspension, a fine (as determined by the "Fine Formula" below), or a combination of a suspension and fine.

**Maximum:** revocation

Tier 2 discipline is recommended for:

- Violations with a serious potential for harm
- Violations which involve greater risk and disregard of public safety

Violations of the following codes are representative of this category:

| Violation Description | Authority |
|---|---|
| Exceeding License Privileges for Commercial Cannabis Activity | B&P §§ 26050 and 26053 |
| Unauthorized Use and Operation of Designated Premises | CCR § 5025 |
| Subletting of Premises | CCR § 5028 |
| Failure to Comply with Track and Trace Reporting and System Reconciliation Requirements | CCR §§ 5049-5051 |
| Failure to Comply with Video Surveillance System Requirements | CCR § 5044 |
| Failure to Comply with Security Personnel Requirements | CCR § 5045 |
| Failure to Verify Age of Customers and Unauthorized Access to Retail Areas | B&P § 26140<br>CCR §§ 5400 and 5402 |
| Failure to Comply with Employee Age Restrictions | B&P § 26140<br>CCR § 5031 |
| Sale or Furnish of Adult-use Cannabis Goods to Minors | B&P §§ 26030(g) and 26140<br>CCR § 5404 |
| Consumption of Cannabis Goods by a Minor on Licensed Premises | B&P § 26200 |
| Failure to Properly Display Cannabis Goods | CCR § 5405 |
| Unauthorized Sale of Non-Cannabis Goods on Premises | CCR § 5407 |
| Exceeding Daily Limits of Cannabis Goods Sales | CCR § 5409 |
| Unauthorized Return of Cannabis Goods | CCR §§ 5053 and 5410 |
| Consumption of Cannabis Goods During Delivery | CCR § 5419 |
| Failure to Ensure Laboratory Testing Arrangements and Quality Assurance | CCR §§ 5304-5307 |
| Failure to Comply with Microbusiness Operations Requirements | CCR § 5500 |
| Failure to Comply with Laboratory Testing Requirements | CCR § 5700 et seq. |
| False or Misleading Declaration of Correction in a Notice to Comply | CCR § 5801 |
| Prohibited Attire and Conduct | CCR § 5806 |

| | |
|---|---|
| Prohibited Entertainers and Conduct | CCR § 5807 |
| Allowing for the Copy or Display of a Fictitious License or a License that is Canceled, Revoked, or Altered | B&P § 119 |
| Misdemeanor Offenses by Licensees | B&P § 125 |
| Discipline by Another Agency | B&P § 141 |
| Failure to Provide Safe Conditions for Inspection | B&P §§ 26030(i) |

**California Code of Regulations Disciplinary Order Guidelines - Tier 3**

**Minimum**: revocation stayed, 45-day suspension, a fine (as determined by the "Fine Formula" below), or a combination of a suspension and fine.

**Maximum**: revocation

Tier 3 discipline is recommended for:

- Knowing or willfully violating laws or regulations pertaining to commercial cannabis activity
- Fraudulent acts relating to the licensee's commercial cannabis business

Violations of the following codes are representative of this category:

| Violation Description | Authority |
|---|---|
| Failure to Notify the Bureau of a Change in Ownership | CCR § 5023 and 5024 |
| Obtaining a License for Premises in Restricted Location | B&P § 26054<br>CCR § 5026 |
| Conducting Commercial Cannabis Activity with Non-Licensees | CCR § 5032(a) |
| Failure to Notify the Bureau of Criminal Acts, Civil Judgments, and Revocation of a Local License, or Other Authorization after Licensure | CCR § 5035 |
| Failure to Notify the Bureau of Significant Discrepancy, Theft, Loss, and Criminal Activity | B&P § 26070 (k)<br>CCR § 5036 |
| Restricting or Hindering the Examination of Books and Records | B&P §§ 26160-26161<br>CCR § 5037(b)-(c) |
| Obstruction of Inspections, Investigations, or Audits | CCR § 5800 |
| Delivery or Transport of Cannabis Goods Outside of California or to a Publicly Owned or Leased Location | B&P § 26080<br>CCR § 5416(b)-(c) |
| Failure to Correct Any Objectionable Conditions on Premises | CCR § 5808(a)-(b) |
| Illegal Sale of Dangerous Drugs, or Other Controlled Substances | CCR § 5808(d) |
| Failure to Pay Fine | B&P § 125.9(b)(5) |
| Engage in Conduct that is Grounds for Denial of Licensure | B&P § 480(a) |
| False Statement in Application | B&P § 480(d) |
| Securing License by Fraud, Deceit, or Misrepresentation. | B&P § 498 |

## Fine Formula

In instances where the Bureau allows a fine to be paid, the following method will be used to calculate the fine.

**Gross Cannabis Sales** divided by **Number of Days Open in Calculation Period = Average Daily Sale Amount**

**Average Daily Sale Amount** multiplied by **Number of Days of the Suspension = Potential Fine Amount**

The books and records of the licensee shall be kept in such a manner that the average daily sale amount and/or the loss of profits from commercial cannabis activity that the licensee would have suffered from a suspension can be determined with reasonable accuracy therefrom, and such books, records, and information shall be accessible to the Bureau to make an accurate and complete determination of any fine amount.

## Minimum and Maximum Fine Amounts

The minimum and maximum fine amount is based on the tier the licensee falls into on annual license fee schedule listed in 16 CCR § 5015.

| License Type | Operations ($Million Max. Per License) | Minimum Fine to Maximum Fine |
|---|---|---|
| Testing Laboratory | Up to 50 Million | $1,000 to $40,000 |
| | Greater than 50 million to 500 Million | $2,000 to $90,000 |
| | Greater than 500 Million | $4,000 to $180,000 |
| Distributor | Up to 2 million | $1,000 to $2,400 |
| | Greater than 2 million to 8 million | $2,000 to $10,000 |
| | Greater than 8 million to 80 million | $4,000 to $72,000 |
| | Greater than 80 million | $8,000 to $250,000 |
| Distributor Transport Only Self-Distribution | Up to 2 million | $1,000 to $2,400 |
| | Greater than 2 million to 8 million | $2,000 to $4,000 |
| Distributor Transport Only | Up to 2 million | $1,000 to $2,400 |
| | Greater than 2 million to 8 million | $2,000 to $5,000 |

| | | |
|---|---|---|
| Retailer | Up to .5 million | $1,000 to $8,000 |
| | Greater than .5 million to 1.5 million | $2,000 to $24,000 |
| | Greater than 1.5 million to 4.5 million | $4,000 to $72,000 |
| | Greater than 4.5 million | $8,000 to $144,000 |
| Microbusiness | Up to .5 million | $1,000 to $10,000 |
| | Greater than .5 million to 1.5 million | $2,000 to $30,000 |
| | Greater than 1.5 million to 4.5 million | $4,000 to $84,000 |
| | Greater than 4.5 million | $8,000 to $240,000 |

## IV. STANDARD CONDITIONS OF PROBATION

The protection of the public is the highest priority of the Bureau. In disciplinary matters where probation as been imposed, the Bureau believes conditions should be imparted to ensure public protection and to allow the probationer the opportunity to demonstrate rehabilitation. The following conditions of probation provide for consumer protection and establish a mechanism to monitor the rehabilitation progress of a probationer. Generally, the Bureau recommends a minimum of three (3) years' probation.

Introductory Language and Conditions 1-7 are required as follows:

1. OBEY LAWS

   Respondent shall obey all state and local laws. A full and detailed account of any and all violations of law shall be reported by the respondent to the Bureau in writing within seventy-two (72) hours of occurrence. To permit monitoring of compliance with this condition, respondent shall submit completed fingerprint forms and fingerprint fees within 45 days of the effective date of the decision, unless previously submitted as part of the licensure application process.

   CRIMINAL COURT ORDERS: If respondent is under criminal court orders, including probation or parole, and the order is violated, this shall be deemed a violation of these probation conditions, and may result in the filing of an accusation and/or petition to revoke probation.

2. SUBMIT WRITTEN REPORTS

Respondent, during the period of probation, shall submit or cause to be submitted such written reports/declarations and verification of actions under penalty of perjury, as required by the Bureau, but no more frequently than once each calendar quarter. These reports/declarations shall contain statements relative to respondent's compliance with all the conditions of the Bureau's Probation Program. Respondent shall immediately execute all release of information forms as may be required by the Bureau or its representatives.

3. REPORT IN PERSON

Respondent, during the period of probation, shall appear in person at interviews/meetings as directed by the Bureau or its representatives.

4. COMPLY WITH CONDITIONS OF PROBATION

Respondent shall fully comply with the conditions of probation established by the Bureau and cooperate with representatives of the Bureau in its monitoring and investigation of the respondent's compliance with the Bureau's Probation Program. Respondent shall inform the Bureau in writing within no more than 15 days of any address change. Upon successful completion of probation, respondent's license shall be fully restored.

5. POSTING OF SIGN

During the period of suspension, Respondent shall prominently post a sign or signs, provided by the Bureau, indicating the beginning and ending dates of the suspension and indicating the reason for the suspension. The sign or signs shall be conspicuously displayed in a location or locations open to and frequented by customers. The location(s) of the sign(s) shall be approved by the Bureau and shall remain posted during the entire period of actual suspension.

Additionally, the Respondent shall circulate a notice of the conditions of probation to all employees, and post the notice in a conspicuous place where notices to employees are posted or available to employees. New employees shall also be provided a copy of the notice of the conditions of probation.

6. MAINTAIN VALID LICENSE

Respondent shall, at all times while on probation, maintain a current and valid license with the Bureau, including any period during which suspension or probation is tolled.

7. COST RECOVERY

Respondent shall pay to the Bureau costs associated with its investigation and enforcement pursuant to Business and Professions Code Section 26031 in the amount of $_____ . Respondent shall be permitted to pay these costs in a payment plan approved by the Bureau, with payments to be completed no later than three months prior to the end of the probation term.

If respondent has not complied with this condition during the probationary term, and respondent has presented sufficient documentation of his or her good faith efforts to comply with this condition, and if no other conditions have been violated, the Bureau, in its discretion, may grant an extension of the respondent's probation period up to one year without further hearing in order to comply with this condition. During the one year extension, all original conditions of probation will apply.

8. LICENSE SURRENDER

During respondent's term of probation, if he or she ceases business or is otherwise unable to satisfy the conditions of probation, respondent may surrender his or her license to the Bureau. The Bureau reserves the right to evaluate respondent's request and to exercise its discretion whether to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances, without further hearing. Upon formal acceptance of the tendered license, respondent will no longer be subject to the conditions of probation. Surrender of respondent's license shall be considered a disciplinary action and shall become a part of respondent's license history with the Bureau.

9. VIOLATION OF PROBATION

If a respondent violates the conditions of his or her probation, the Bureau after giving the respondent notice and an opportunity to be heard, may set aside the stay order and impose the stayed discipline (revocation/suspension) of the respondent's license. If during the period of probation, an accusation or petition to revoke probation is filed against respondent's license, or the Bureau has served the respondent a notice of intent to set aside the stay, the Bureau shall have continuing jurisdiction, and the probationary period shall automatically be extended and shall not expire until final resolution of the matter.

## VI. INTRODUCTORY LANGUAGE AND OPTIONAL TERMS AND CONDITIONS OF PROBATION

The following introductory language and all standard probation conditions are to be included in probationary decisions/orders. For applicants, cost recovery conditions do not apply. For licensees, all standard probation conditions apply. Optional terms and conditions may be included in orders of probation based upon violations.

## INTRODUCTORY LANGUAGE FOR ALL ORDERS

IT IS HEREBY ORDERED that License Number _____ issued to Respondent_____ is [revoked/suspended/fined] [for/in the amount of] [days/amount], [however, the revocation is stayed] and respondent is placed on probation for _____ years on the following conditions.

SEVERABILITY CLAUSE – Each condition of probation contained herein is a separate and distinct condition. If any condition of this Order, or any application thereof, is declared unenforceable in whole, in part, or to any extent, the remainder of this Order, and all other applications thereof, shall not be affected. Each condition of this Order shall separately be valid and enforceable to the fullest extent permitted by law.

# Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds

*2nd Edition*

US Food & Drug Administration
Office of Foods and Veterinary Medicine

April 2015

## ACKNOWLEDGMENT

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***Center for Food Safety and Applied Nutrition***
Office of Applied Research and Safety Assessment
Office of Food Safety
Office of Regulatory Science

***Center for Veterinary Medicine***
Office of Research

***National Center for Toxicological Research***
Division of Microbiology

***Office of Regulatory Affairs***
Office of Regulatory Science
ORA Cadre of Microbiology Subject Matter Experts

## Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Ed.

### APPROVAL PAGE

This document is approved by the FDA Foods and Veterinary Medicine (FVM) Science and Research Steering Committee (SRSC). The FVM SRSC Project Manager is responsible for updating the document as change requirements are met, and disseminating updates to the SRSC and other stakeholders, as required.

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ORA, Member of the ORA Scientific Advisory Council

# US Food & Drug Administration
# Office of Foods and Veterinary Medicine

# Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds
## *Second Edition*

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## List of Tables

# 1.0 INTRODUCTION

## 1.1 Purpose

The Foods and Veterinary Medicine (FVM) Enterprise within the U.S. Food & Drug Administration is responsible for ensuring the safety of the nation's food and feed supply. FDA accomplishes this through education; inspection; data collection; standards setting; prompt investigation of outbreaks; and, enforcement actions when appropriate. The effectiveness of the FVM Enterprise is highly dependent on the quality and performance of the laboratory methods used within the FDA. To ensure that all laboratory methods meet the highest analytical standards possible for their intended purpose, the FDA Office of Foods and Veterinary Medicine (OFVM) through the Science and Research Steering Committee (SRSC) has established these criteria by which all FVM microbiological methods shall be evaluated and validated.

## 1.2 Scope

These criteria apply to all FDA laboratories that develop and participate in the validation of analytical food and feed methods for Agency-wide implementation in a regulatory capacity. This includes all research laboratories, and ORA labs where analytical methods may be developed or expanded for potential regulatory use. At the time of final approval by the OFVM and the SRSC, this document will supersede all other intra-agency documents pertaining to food- and feed-related method validation criteria for microbial analytes. In addition, this guidance is a forward-looking document; the requirements described here will only apply to *newly*-developed methods and those for which significant modifications have been made to an existing method. Once a method has been validated, it can be implemented by other laboratories following the method verification process.

## 1.3 Administrative Authority and Responsibilities

All criteria established in this document for analytical method validation have been adopted and approved by the OFVM and the SRSC. As stated in the Methods Development, Validation and Implementation Program SOP (APPENDIX 3), The Method Validation Subcommittee (MVS) will have oversight responsibility for all collaborative validation studies (See Section 2.2.2.3).

## 1.4 The Method Validation Subcommittee

Under the authority of the SRSC, a Microbiology Methods Validation Subcommittee (MMVS) will oversee all microbiology method validation concerns. The MMVS is governed by the organizational structure, roles and responsibilities as detailed in its charter (See APPENDIX 2). Briefly, the MMVS will oversee and coordinate – in collaboration with the originating laboratory – all collaborative laboratory validation studies (planning and implementation) for microbiological methods developed within the FDA FVM Enterprise to support regulatory analytical needs. This includes the evaluation of Single Laboratory Validation (SLV) results and the evaluation of any subsequent collaborative validation study plan. Unless

otherwise stated, most correspondence between the method developer(s) and the MMVS will be by email using the following address: Microbiology.MVS@fda.hhs.gov.

## 1.5 General Responsibility of the Originating Laboratory

It is the responsibility of the originating (developing) laboratory to ensure proper adherence to all criteria described in the document. The originating laboratory must work in close consultation with the MMVS and/or its designated Technical Advisory Group (TAG) throughout the collaborative laboratory validation process. It will be the responsibility of the originating laboratory to include their respective QA/QC manager in all aspects of the validation process and to ensure proper adherence to all criteria described in this document.

## 1.6 Method Validation Definition

Method validation is a process by which a laboratory confirms by examination, and provides objective evidence, that the particular requirements for specific uses are fulfilled. It serves to demonstrate that the method can detect and identify an analyte or analytes:

- In one or more matrices to be analyzed.
- In one or more instruments or platforms.
- With a demonstrated sensitivity, specificity, accuracy, trueness, reproducibility, ruggedness and precision to ensure that results are meaningful and appropriate to make a decision.
- Reliably for its intended purpose. Intended purpose categories include, but may not be limited to emergency/contingency operations; rapid screening and high throughput testing; and confirmatory analyses.
- After the method developer has conducted experiments to determine or verify a number of specific performance characteristics that serve to define and/or quantify method performance.

## 1.7 Applicability

This document establishes evaluation criteria for methods to detect, identify, and quantify all microbial analytes that may now be, or have the potential to be associated with foods and feeds *i.e.* any microbiological organism of interest (target organism) or the genetic material *i.e.* DNA, RNA, toxins, antigens, or any other product of these organisms. If not specifically identified, all information contained in the accompanying tables should be extrapolated to the microbial analyte of interest. Such applicable areas of methods development and evaluation include, but are not limited to, the following:

- Qualitative assays *i.e.* detection assays
- Quantifiable assays *i.e.* real-time PCR
- Analyte-specific

- Bacteriological, *e.g.*
  - *Salmonella* spp.
  - Pathogenic *Escherichia coli*
  - *Listeria monocytogenes*
  - *Shigella* spp.
  - *Vibrio* spp.
  - *Campylobacter* spp.
- Microbial toxins *(excluding marine biotoxins. See Chemistry method validation guidelines)*
- Viral pathogens, *e.g.*
  - Hepatitis A virus
  - Norovirus
  - Enterovirus
- Parasitic protozoan pathogens, *e.g.*
  - *Cryptosporidium*
  - *Cyclospora cayetanensis*
- Indicator organisms

- Bioengineered analytes, *e.g.*
  - Genetically-modified foods (GMOs)
- Applications
  - Pre- and selective enrichment
  - Microbial analyte recovery and concentration
  - Screening, high-throughput, confirmation
- Procedures
  - Phenotypic, *e.g.*
    - Biochemical characterization for identification
    - Antibiotic resistance traits for identification
    - Antigenic characterization for identification
  - Genetic, *e.g.*
    - Nucleic acid isolation/concentration/purification
    - Polymerase Chain Reaction
      - Conventional
      - Real-time
      - Reverse transcription
    - Sequencing, *e.g.*
      - Whole genome
      - Selective sequencing
      - Single nucleotide polymorphism (SNP) analysis
    - Strain-typing applications
- Immunological
  - Antibody capture
  - ELISA
  - Flow cytometry

## 1.8 Requirements

Method validation shall be required for:

- Submission of a new or alternate method.
- Major modifications to an existing, validated method (See Section 5.0).

## 2.0 CRITERIA AND GUIDANCE FOR THE VALIDATION OF FDA-DEVELOPED METHODS

This section provides validation criteria and guidance for all FVM-developed or any existing validated method(s) that has been significantly modified (*See* Section 5.0).

### 2.1 Validation Definitions

#### 2.1.1 The Reference Method

The reference method is defined as that method by which the performance of an alternate method is measured or evaluated. Validation studies must include comparison to a recognized reference method to demonstrate equivalence or increased performance, the significance of which must be determined statistically. For bacterial analytes, reference methods are generally culture-based and result in a pure isolate. The FDA Bacteriological Analytical Manual (BAM), the USDA Microbiology Laboratory Guidebook (MLG) and ISO culture methods contain recognized reference culture methods. FDA BAM reference methods take precedence over all other reference methods unless otherwise determined by the MMVS. It is recognized that this requirement may either not be practical or possible in all instances. In such cases, consultation between the originating laboratory and the MMVS will be necessary to define the most appropriate reference method. ***All*** new methods ***must*** be validated against an agreed-upon reference method if existing.

#### 2.1.2 The Alternate Method

The alternate method refers to the newly developed or modified method that is to be evaluated against the performance of a recognized reference method by a defined validation process.

#### 2.1.3 The Originating Laboratory

The originating laboratory refers to the laboratory that developed the method and has completed the SLV requirements.

**NOTE:** An "originating laboratory" can be more than a single laboratory when 2 or more laboratories combine their resources to develop and validate a method. In such cases, none of the laboratories so combined may act as a Collaborating Laboratory.

#### 2.1.4 The Collaborating Laboratory

The collaborating laboratory refers to the laboratory (or laboratories) other than the originating laboratory involved in multi-laboratory method validation studies.

## 2.2 The Method Validation Process

Within the FVM Enterprise, method validation exercises confirm by examination (and the provision of objective evidence) that the particular requirements for a method have been fulfilled. All methods used by the FDA in support of its regulatory and compliance roles must be validated according to the guidelines established by the FVM Enterprise. Three levels of scrutiny are defined below and serve to demonstrate that the method can detect, identify and, where applicable, quantify an analyte or analytes to a defined standard of performance. The hierarchy of criteria within the validation process also provides general characteristics on the method's utility and insights for its intended use.

### 2.2.1 Emergency Usage (Level One)

This level has the lowest level of validation. All the work will have been done by one or more labs. Sensitivity and specificity (inclusivity and exclusivity) has been tested, but only included a limited number of strains. The MMVS, Agency subject matter experts (SMEs) and the originating laboratory may identify additional criteria for evaluation. Once the crisis has past and it has been determined that there is a need for further validation, procedures outlined in this document must be followed.

**Intended Use:** Emergency needs. These are methods developed or modified for the detection of an analyte, or a matrix not previously recognized or identified as a threat to food safety or public health. Performance of the method at this level will determine, in part, whether further validation is useful or warranted.

**NOTE:** *Under emergency situations where the rapid development and deployment of a method is needed to immediately address an outbreak event, Level 1 - Emergency Use criteria should be followed as closely as the situation will allow.*

### 2.2.2 Method Validation Levels (for Non-Emergency Use Methods)

#### 2.2.2.1 Single-laboratory Validation (Level Two - Part a)

The originating lab has done a more comprehensive initial study with defined inclusivity/exclusivity levels as shown in Tables 1. If available, a comparison has been done to an existing reference method. Results of the SLV has been evaluated and approved by the MMVS. This is the first step in the validation process for methods designed for routine regulatory applications.

**Intended Use:** Methods validated to this level of scrutiny can be used immediately for emergencies. Slightly higher false-positive rates may be acceptable as all samples analyzed will require confirmatory testing.

#### 2.2.2.2 Independent Laboratory Validation (Level Two - Part b)

One other independent laboratory has participated in the validation study using the method of the originating lab and criteria described in Table 1. Successful completion of this level of scrutiny and the approval of the MMVS are prerequisite steps prior to any collaborative validation study.

**Intended Use:** Methods validated to this level of scrutiny can be used immediately for emergencies. Slightly higher false-positive rates may be acceptable as all samples analyzed will require confirmatory testing.

#### 2.2.2.3 Collaborative Validation Study (Level Two – Part c)

A Collaborative study is an inter-laboratory study in which each laboratory uses the defined method of analysis to analyze identical portions of homogeneous materials to assess the performance characteristics obtained for that method of analysis (W. Horwitz, IUPAC, 1987). It is designed to measure inter-laboratory reproducibility, so that it can be determined if the method can be successfully performed by laboratories other than the originating laboratory. For methods having more than one sample preparation or enrichment scheme, it is necessary to test one matrix per sample preparation or enrichment scheme.

The criteria defined for this level of scrutiny (to be performed by the originating and collaborating labs) are closely aligned with other recognized and established validation criteria for collaborative studies *e.g.* AOAC, ISO. This includes criteria for inclusivity/exclusivity, analyte contamination levels, competitor strains, aging, and a comparison to an existing, recognized reference method when available.

**Intended Use**: All methods validated to this level of scrutiny are acceptable for use in any and all regulatory circumstances *e.g.* confirmatory analyses; regulatory sampling, outbreak investigations, and surveillance and compliance support.

### 2.3 Validation Criteria

Tables 1, 2, 3 and 4 contain the general criteria that must be met in order to successfully achieve a defined level of validation for a new or modified method. Table 1 describes general guidelines for qualitative methods to detect conventional microbial foodborne pathogens. Table 2 applies to detection methods for microbial analytes that face unique isolation and/or enrichment challenges. Table 3 describes general guidelines for identification or confirmatory methods. Table 4 describes general guidelines for quantifiable methods. The criteria contained within these tables also distinguish between qualitative and quantifiable methods; and, those requirements to be carried out by the originating and collaborating laboratories respectively.

## 2.3.1 Validation Criteria for Qualitative Methods to Detect Conventional Microbial Food-borne Pathogens

### 2.3.1.1 Definition

A method that identifies analyte(s) based on chemical, biological, or physical properties; method of analysis whose response is either the presence or absence of the analyte detected either directly or indirectly in a certain amount of sample. Most qualitative methods are or can be made at least "semi-quantitative" to provide rough estimates of the amount of analyte present.

### 2.3.1.2 Criteria

Tables 1 pertains to bacterial pathogens (and other pathogenic microorganisms) that meet the following general characteristics:

- Not limited by strain availability; ability to fully comply with inclusivity and exclusivity requirements.
- Are capable of cultural enrichment in a timely manner.
- Can be enumerated.

**Table 1- General Guidelines for the Validation of Qualitative Detection Methods for Microbial Analytes**

| | Emergency | Non-Emergency Validation Processes | | |
|---|---|---|---|---|
| **Criteria** | **Emergency Use** | **Single Laboratory Validation Study** | **Independent Laboratory Validation Study** | **Collaborative Validation Study** |
| Participating Laboratory | Originating Laboratory | Originating Laboratory | Collaborating Laboratory | Collaborating Laboratories |
| # of target organism (inclusivity)[a] | ‡TBD | 50 (unless 50 aren't available)[b,c] | ᶠNA | ᶠNA |
| # of non-target organism (exclusivity) [a] | ‡TBD | 30 strains[d] | ᶠNA | ᶠNA |
| # of laboratories providing usable data | 1 | 1 | 1 | 10 |
| # of foods | 1or more[e] | 1or more[e] | 1or more[e] | 1or more[e] |
| # of analyte levels/food matrix | ‡TBD | Two inoculated levels[f] and one uninoculated level | Two inoculated levels[f] and one uninoculated level | 3 levels: One inoculated level[f], one at 1 log higher[g] and one uninoculated level |
| Replicates per food at each level tested | ‡TBD | 20 for the fractional level (5 each for the uninoculated and high levels) | 20 for the fractional level (5 each for the uninoculated and high levels) | 8 |
| Aging of inoculated samples prior to testing | No | Yes[h] | Yes[h] | Yes[h] |
| Addition of competitor strain[i] | Normal background flora | In 1 food at +1 log>analyte at fractional positive[f] analyte level | In 1 food at +1 log>analyte at fractional positive[f] analyte level | In 1 food at +1 log>analyte at fractional positive[f] analyte level |
| Reference Method Comparison Requirement[j] | ‡TBD | Yes, if available | Yes, if available | Yes, if available |

[a]Using pure cultures without a food matrix.
[b]Each at $10^3$ CFU/mL following the method protocol (1 $\log_{10}$ above the LOD for other methods); or $10^3$ CFU/reaction for molecular methods *e.g.* PCR.
[c]100 serotypes for Salmonella testing.
[d]At $10^3$ CFU/mL for non-target organisms grown in a non-selective rich medium.
[e]For FDA regulatory use, methods are only valid for foods that have been tested; the MMVS may require that a new method be validated for 3 foods within a food category (See APPENDIX 5). See Section 5 for further guidance on matrix extension criteria.
[f]Must be adjusted to achieve fractional positive results (one or both methods *i.e.* the reference and alternate methods must yield 50%±25% of tests positive) at this level; the high level inoculum should be approximately1 log greater than that used to achieve fractional results. All 5 replicates at the high inoculum should yield positive results.
[g]All test samples inoculated at this level must yield 100% positive results
[h]Period of aging depends on food being tested. Perishable foods should be aged under refrigeration for 48 – 72 h. Frozen and shelf stable foods should be aged for a minimum of 2 weeks at -20°C or at room temperature, respectively.
[i]An appropriate competitor is one that gives similar reactions in enrichment and detection systems. Natural background microflora can fulfill this requirement as long as it present in the matrix at a level 1 log greater than the target analyte.
[j]Independent Laboratory and Collaborative Validation Studies should use the most effective reference method available.
‡TBD to be determined in consultations with the originating laboratory, the MMVS, and subject matter experts.
ᶠ Not Applicable

## 2.3.1.3 Detection of Microbial Analytes That Present Unique Isolation and/or Enrichment Challenges†

Tables 2 provides validation criteria for microbial pathogens characterized as difficult to isolate, limited resources for extensive inclusivity and

exclusivity studies, and either non-culturable for enrichment purposes or, enrichment cannot be accomplished in a timely manner.

**Table 2 - General Guidelines for the Validation of Qualitative Detection Methods for Microbial Analytes - Unique Isolation and/or Enrichment Challenges †**

| | Emergency | Non-Emergency Validation Processes | | |
|---|---|---|---|---|
| **Criteria** | **Emergency Use** | **Single Laboratory Validation Study** | **Independent Laboratory Validation Study** | **Collaborative Validation Study** |
| Participating Laboratory | Originating Laboratory | Originating Laboratory | Collaborating Laboratory | Collaborating Laboratories |
| # of target organism (inclusivity)[a] | ‡TBD | ‡TBD | ¶NA | ¶NA |
| # of non-target organism (exclusivity)[a] | ‡TBD | ‡TBD | ¶NA | ¶NA |
| # of laboratories providing usable data[b] | 1 | 1 | 1 | 5[¥] |
| # of foods | 1 or more[¥] | 1 or more[¥] | 1 or more[¥] | 1 or more[¥] |
| # of analyte levels/food matrix | ‡TBD | One inoculated level[c] and one uninoculated level | One inoculated level[c] and one uninoculated level | 3 levels: One inoculated level[c], one at 1 log higher[d] and one uninoculated level |
| Replicates per food at each level tested | ‡TBD | 3 | 3 | 8[¥] |
| Reference Method Comparison Requirement[e] | ‡TBD | Yes, if available | Yes, if available | Yes, if available |

[a]Using pure cultures without a food matrix.
[b]Labs providing data are required to run study on same PCR platform.
[c]Must be adjusted to achieve fractional positive results (one or both methods *i.e.* the reference and alternate methods must yield 50%±25% of tests positive) at this level, advisable to include when possible one additional level at +1 log.
[d]All test samples inoculated at this level must yield 100% positive results.
[e] Independent Laboratory and Collaborative Validation Studies should use the most effective reference method available.
[†]Such examples include but are not limited to RNA food-borne viruses, and protozoan parasites. See APPENDIX 3 Sections V and VI.
[‡]TBD to be determined in consultations with the originating laboratory, the MMVS, and subject matter experts.
[¶] Not Applicable.
[¥]Where circumstance and resources permit.

## 2.3.2 Validation Criteria for Identification Methods

### 2.3.2.1 Definition

A method used to confirmation the identity of a microbial analyte *e.g.* serotyping.

### 2.3.2.2 Criteria

**Table 3- General Guidelines for the Validation of Identification Methods for Microbial Analytes**

| | Non-Emergency Validation Processes | | |
|---|---|---|---|
| **Criteria** | **Single Laboratory Validation Study** | **Independent Laboratory Validation Study** | **Collaborative Validation Study** |
| **Participating Laboratory** | **Originating Laboratory** | **Collaborating Laboratory** | **Collaborating Laboratories** |
| # of target organism (inclusivity)[a] | ≥50 (unless 50 aren't available)[b,c] | 1[c] | 12[c] |
| # of non-target organism (exclusivity) [a] | ≥30 strains [b,c] | 1[c] | 12[c] |
| # of laboratories providing usable data | 1 | 1 | 10 |
| Replicates[d] | 3 | 3 | 3 |
| Reference Method Comparison Requirement | Yes, if available | Yes, if available | Yes, if available |

[a]At $10^3$ CFU/mL for target organisms and non-target organisms grown in a non-selective rich medium. $10^3$ CFU/reaction for molecular methods *e.g.* PCR.
[b]100 serotypes for *Salmonella* testing.
[c]Should be evaluated together in one single study; inclusive and exclusive samples should be intermingled and blinded
[d]All replicates must yield the correct answer

## 2.3.3 Validation Criteria for Quantifiable Methods to Detect Conventional Microbial Food-borne Pathogens

### 2.3.3.1 Definition

A method that provides an estimate of the amount of analyte present in the test sample, expressed as a numerical value in appropriate units, with trueness and precision which are fit for the intended purpose.

### 2.3.3.2 Criteria

**Table 4- General Guidelines for the Validation of Quantifiable Detection Methods for Microbial Analytes**

| | Non-Emergency Validation Processes | | |
|---|---|---|---|
| Criteria | Single Laboratory Validation Study | Independent Laboratory Validation Study | Collaborative Validation Study |
| Participating Laboratory | Originating Laboratory | Collaborating Laboratory | Collaborating Laboratories |
| # of target organism (inclusivity) | 50 (unless 50 aren't available) | NA[f] | NA[f] |
| # of non-target organism (exclusivity) | 30 strains | NA[f] | NA[f] |
| # of laboratories providing usable data | 1 | 1 | 10 |
| # of foods | 1 or more[a] | 1 or more[a] | 1 or more[a] |
| # of analyte levels/food matrix[f] | 4 levels: Low medium and high inoculum levels[b] and one uninoculated level | 4 levels: Low medium and high inoculum levels[b] and one uninoculated level | 4 levels: Low medium and high inoculum levels[b] and one uninoculated level |
| Replicates per food at each level tested | 5 replicates per level for a total of 20 replicates per method | 5 replicates per level for a total of 20 replicates per method | Two test portions per level for a total of 8 test portions |
| Aging of inoculated samples prior to testing | Yes[c] | Yes[c] | Yes[c] |
| Addition of competitor strain[d] | In 1 food at +1 log>analyte at highest analyte level | In 1 food at +1 log>analyte at highest analyte level | In 1 food at +1 log>analyte at highest analyte level |
| Reference Method Comparison Requirement | Yes, if available | Yes, if available | Yes, if available |
| Confirmation of Test Portions | NA[f] | NA[f] | Yes, follow the reference method |

[a]For FDA regulatory use, methods are only valid for foods that have been tested; validation can be extended to other foods by further testing. See section 5.1
[b]The low level should be at or near the limit of detection; medium and high levels should be chosen to span the analytical range of the alternate method.
[c]Period of aging depends on food being tested. Perishable foods should be aged under refrigeration for 48 – 72 h. Frozen and shelf stable foods should be aged for a minimum of 2 weeks at -20°C or at room temperature, respectively.
[d]An appropriate competitor is one that gives similar reactions in enrichment and detection systems. Natural background microflora can fulfill this requirement as long as it present in the matrix at a level 1 log greater than the target analyte.
[f] Not Applicable

## 2.4 Method Validation Operational Aspects

### 2.4.1 General Considerations

- All correspondence *e.g.* proposals, validation reports etc., with the MMVS will be initiated via email using the following address: Microbiology.MVS@fda.hhs.gov.
- As defined in the SRSC Document titled "Method Development, Validation and Implementation SOP (See APPENDIX 3), all method validation plans must be

submitted to and approved by the MMVS prior to initiating any methods validation work beyond the single lab validation stage. See APPENDIX 4 for proposal formatting.

- The number of laboratories submitting usable data in all the above tables represents the minimum number allowable for a successful validation study. It is suggested that 4 additional labs be considered for participation, since a variety of unforeseen circumstances can cause data sets to be rejected.
- The following elements must be addressed in all proposals for method validation studies (in non-emergency use situations).

  - Intended use or applicability statement for the method being validated.
  - Applicability of paired vs. unpaired sampling/testing.
  - Statistical methods must be employed to verify equivalent or statistically-significant improvement of performance between the new method and the reference method (or in some cases, the originally validated method) to include but not limited to sample means and the degree of accuracy. The MVS biostatistician will provide guidance on applicable statistical tools that will be employed on a case-by-case basis (See 2.4.2 Assessment for additional details).
  - Use of an appropriate reference method as determined in consultation with the MMVS. The reference method shall never be modified; comparison with a modified reference method renders the validation study invalid.
  - Where possible, the use of an accredited independent source for sample preparation and distribution.
  - Strain selection for inclusivity and exclusivity testing – This facet of the validation study it to assess the reliability and specificity of the alternate method.

    - Individual laboratories within the FVM research enterprise maintain their own inventories of microbial analyte collections. These collections, strains and serovars derived from food surveillance programs, food-borne outbreak investigations, and clinical specimens, are available to all Agency scientists. Access is governed by "U.S. Food and Drug Administration Foods Program Internal Strain Sharing Standard Operating Procedure" (http://inside.fda.gov:9003/downloads/OC/OfficeofFoods/UCM353743.pdf).
    - The choice of inclusivity strains should reflect the genetic, serological, and/or biochemical diversity of the organisms involved, as well as other factors such as virulence, frequency of occurrence and availability. Inclusivity testing is performed on purified cultures.
    - The choice of exclusivity strains should closely reflect related, potentially cross-reactive organisms. Other factors such as virulence, frequency of occurrence and availability should be considered. Exclusivity testing is performed on purified cultures.

- Species/strains specified for use in inclusivity and exclusivity panels must be traceable to the source. The source and origin of each species/strain should be documented. See Appendix 6 for suggested inclusive and exclusive microbial analytes. This is not an exhaustive list and should serve only as a reference resource and a guide to aid the developer.
- It is understood that it is not always possible to meet the inclusivity/exclusivity requirements listed herein. For example, only limited numbers of strains may be available for emerging pathogens, certain viruses or parasites. Under such circumstances, the MMVS or its designee will work in concert with the originating laboratory to test their methods with the maximum number of available strains when the developer is unable to comply with the requirements of this document.

- Suitability and availability of naturally-contaminated samples in the proposed validation study.
- Inoculum preparation, spiking methodology, and uniformity of contamination (when artificially-contaminated samples will be used).
- Sample preparation, naturally-occurring microflora, and the requirement for aerobic plate counts (APC) to verify background microflora.
- Need for inclusion of competitive microflora. For food matrices that exhibit low naturally-occurring microflora background (as determined by APC), validation studies will adhere to AOAC-established parameter *i.e.*1 log greater than microbial analyte being tested. Selection of competitive microflora to be used will be done in consultation with the MMVS.
- Selection of spiking levels (when artificially-contaminated samples will be used).
- Matrix aging to assess method robustness.
- Microbial analyte stress, cell injury, and matrix-derived inhibition of analyte enrichment/growth.
- Selection of appropriate foods. Food matrices will be validated individually based on the historical outbreak record and epidemiological link between matrix, pathogen, and illness. Some examples are provided in Appendix 5. Extension of a method to include additional food matrices will require additional validation studies. See Sections IV and V.
- Formation of composited samples. In some instances, it may be necessary to validate composited samples. In the case of *Salmonella*, an analytical unit is 25 g and a composite sample is 375 g. A composite test portion is formed by adding fourteen uninoculated 25 g test portions to one inoculated 25 g test portion for a total of 375 g. The composite is compared to a 25 g inoculated test portion that is analyzed with the reference method.
- Inocula designed to yield fractional positive results. Samples for both the reference method and the test method must achieve 50%±25% positive results (See APPENDIX 1: Glossary of Terms, for a complete description of fractional recovery).

### 2.4.2 Assessment of Validation Results

- Acceptable false negative and false positive rates will be established in consultation with the MMVS. Factors that will influence this decision may include but not be limited to the replicate number and intended use (emergency, screening, confirmatory).
- False positive and false negative rates for a collaborative study will be evaluated in total (across all labs/data sets).
- Method equivalence determinations and employing appropriate statistical measurements. Statistical algorithms must be employed to test for significance differences (superiority or equivalence) and for data disqualification *(see below)*, the preferred method of statistical analysis is Relative Limit of Detection (RLOD). Selection of a statistical approach will be dictated by the type and scope of the study and will be determined through consultations between the originating lab and the MMVS during the planning phase of any validation study.
- Data sets derived from a validation exercise can be disqualified. Examples include but may not be limited to:

    - Negative controls (un-inoculated controls) yield a positive outcome-an indicator of lab/operator error.
    - Deviation from the prescribed method.
    - Quality control deficiencies e.g. homogeneity and stability. Statistically-supported outliers (Quantifiable methods).
    - Failure to achieve fractional results within specified ranges (across all labs/data sets).

## 3.0 CRITERIA AND GUIDANCE FOR THE VALIDATION OF FDA-DEVELOPED MOLECULAR-BASED ASSAYS

These criteria and guidelines are intended to support method validation efforts for developers of molecular-based assays, *e.g.* PCR to be used to confirm the identity or exclusion of isolated colonies.

This guidance is intended to govern validation studies for either conventional or real time PCR assays. If validating a real time assay, the platform and chemistry must be specified. It is strongly recommended that a real time assay be validated on two to three other platforms i.e. thermal cyclers or workstations. Other molecular methods should provide detailed chemistry and platform prerequisites and include multiple platforms where possible.

The criteria necessary to determine four levels of validation for qualitative PCR assays for bacteria are the following:

### 3.1 Inclusivity and Exclusivity

The inclusivity and exclusivity requirements described above apply here. The amount of template, whether using bacterial cells or purified nucleic acid, should be comparable for both inclusivity and exclusivity panels.

It is expected from the originating laboratory that all primer and/or probe sequences would initially be screened for uniqueness by searching a bacterial genomic database for homology. It is recommended that a BLAST search be performed against the GenBank non-redundant database.

### 3.2 Target Gene(s) and Controls (Positive and Negative).

Molecular-based assays to target gene(s) from a specific microbial analyte, whether to a virulence factor or taxonomic identifier (e.g. 16S DNA), must have demonstrable specificity (inclusivity and exclusivity) for that particular pathogen. Positive and negative control strains and reactions should be incorporated into the assay evaluation. Internal amplification controls for real-time PCR assays ***are required*** for regulatory food or environmental sample analyses.

### 3.3 Comparison to the Reference Method

The originating laboratory will compare the PCR-based method to bacteriological, biochemical, and/or serological reference methods. PCR-based methods may only be compared to PCR-based reference identification methods when bacteriological, biochemical, and/or serological reference methods are unavailable.

## 4.0 CRITERIA AND GUIDANCE FOR THE VALIDATION AND VERIFICATION OF COMMERCIALLY- AVAILABLE MICROBIOLOGICAL DIAGNOSTIC KITS AND PLATFORMS

### 4.1 Definitions

#### 4.1.1 Validation of an Alternative Method

Demonstration that adequate confidence is provided when the results obtained by the alternative method *i.e.* the commercially-available kit, are comparable to or exceed those obtained using the reference method using the statistical criteria contained in the approved validation protocol.

#### 4.1.2 Verification

Method verification is a process by which a laboratory confirms by examination, and provides objective evidence, that the particular requirements for specific uses are fulfilled. It serves to demonstrate that the method can detect and identify an analyte or analytes:

- The confirmation by examination and the provision of objective evidence that specified requirements have been fulfilled.
- To assess the performance of a method in the user's laboratory against the specifications of the method established during the validation.

- To assess the method performance on items included in the scope of the method and tested routinely by the user laboratory.
- To demonstrate that the method functions (without any adaptation) in the user's laboratory on matrices not included in the original method validation.

## 4.2 Criteria

### 4.2.1 Commercially-available Microbiological Diagnostic Kits Whose Performance Parameters Have been Fully Validated in a Multi-laboratory Collaborative Study Monitored and Evaluated by an Independent Accrediting Body *e.g.* AOAC-OMA, AFNOR, etc.

Each lab must perform an in-house verification for the *"first use"* of an alternate method in this category. For subsequent use(s) of the method, lab controls will be used per lot to re-verify the method.

#### 4.2.1.1 Verification Requirements *(per lab)*

- Six replicates of the inoculated matrix and six replicates of the un-inoculated matrix are tested and confirmed by both the alternative and the reference method.
- If no false positive or false negative results are obtained, then the new matrix is verified.
- Each commodity to be tested should be spiked with a level close to the detection limit, usually <30 cfu of analyte per 25 g food sample or any other specified test portion to determine if there is any interference from the matrix.
- If unacceptable false positive or false negative results are observed (as defined for the intended use of the method), then the study must be expanded to a full SLV (Table1) to define the operating characteristics of the method with the new matrix. Consult Section V: Food Matrix Extension for more detailed information.

**NOTE:** The verification criteria described above apply only for foods which were part of the collaborative study by an independent accrediting body. The use of such kits for food matrices that were not included in the original collaborative study must be preceded by a food matrix extension study. (See Section 5: Food Matrix Extension)

### 4.2.2 Commercially-available Microbiological Diagnostic Kits Whose Performance Parameters are Supported by Data Obtained Through an Independent Laboratory Validation Protocol and Evaluated by an Independent Accrediting Body *e.g.* AOAC-RI.

All methods fitting into this description ***must*** be validated according to the criteria defined for Agency-developed (FDA) microbiology methods (*See* Section 2).

## 5.0 METHOD MODIFICATION AND METHOD EXTENSION CRITERIA FOR EXISTING VALIDATED MICROBIOLOGY METHODS

Modifications to an existing validated method may be made for any number of reasons and may or may not affect the established validated performance parameters of the original method. There is no *"one size fits all"* rule or set of rules to govern how a modification will be addressed.

Some modifications (*e.g.* ease-of-use capabilities, availability/substitution of reagents or instrumentation, sample handling/sample processing adaptations, etc.) may only necessitate verification against the original method according to criteria detailed in Section 4.2.1.1., whereas other modifications may require significant validation data to support their use. It is recommended that statistical analyses be performed on the verified performance specifications to support implementation of the modification. These include:

- The *t* test for significance of difference between the two sample means to determine degree of accuracy. The *t* Stat value must be less than or equal to the *t* critical value.
- The F test for significance of difference between the two sample variances to determine degree of precision. The F value must be less than or equal to the F critical value.

More extensive modifications that may influence method sensitivity, specificity, precision and accuracy (quantifiable methods), *e.g.* changes in sample preparation procedures, time/temperature requirements for non-selective and selective enrichment media; or, altering chemistry parameters for molecular methods for example may require either limited (SLV or Independent Laboratory Validation Study) or a Collaborative Validation Study as described in Table 1.

Any decision on how such modifications are viewed and the approach to be taken will reside with the MMVS.

Specific criteria for matrix and platform extension to existing methods are described in greater detail in Sections 5.1 and 5.2

### 5.1 Matrix Extension

FDA ORA microbiology labs analyze a huge variety of food matrices. Even so, methods used in FDA field laboratories for regulatory purposes must be evaluated for <u>*each*</u> food.

Very often however, validation studies can neither address all the varied matrices nor fully anticipate what matrix or matrices will be involved in emergency situations

or outbreak investigations – two scenarios where samples must be analyzed immediately.

Though it is generally assumed that the more closely related a new food matrix is to a previously-validated matrix for the detection of a defined analyte, the greater the probability that the method will perform similarly with the new matrix, the method must nonetheless be verified for all new matrices. This is to ensure that the new matrix will neither produce high false positive (matrix is free from cross reactive substances) nor high false negative rates (matrix is free of inhibitory substances).

As described below, either a verification process or additional validation studies will be required before any given validated method can be used to test a food (or foods) not included in the original method validation. Close consultation between method developers, laboratory managers, QMS managers and the MVS will aid in determining which approach is more applicable for any given situation.

**NOTE:** Criteria described in sections 5.1.1 and 5.1.2 only apply to situations in which no additional modifications to the method have been made. In those cases where food matrix extension is accompanied by additional modifications to the method, an SLV or Independent Laboratory Validation as described in Table 1 may be required. This decision will be at the discretion of the MMVS.

### 5.1.1 Matrix Extension Guidance for New Foods From the Same Category Used for the Original or Subsequent Validation Studies

In instances where a method will be used to test a food (or foods) from the same category of food (See APPENDIX 5) included in the original validation study, ORA laboratories will analyze the matrix in question concurrently with a matrix spike. The matrix spike will consist of a 25 gram sample of the product spiked with an inoculum of 30 cells or less of the target analyte. Negative spike results invalidate the analysis and the sample must be analyzed using the conventional culture procedure.

ORA labs may continue to perform individual sample matrix spikes for matrices that have not been fully validated for the method. Matrix spike results will be entered into Field Accomplishment Computerized Tracking System (FACTS) and data will be evaluated and classified according specific food, and matrix spike results. When a specific food has yielded at least seven positive and no negative results using matrix spikes; or, a >95% confidence level (19 of 20 positives), the method will be considered verified for that food product. The method can then be used for that food without further positive spike controls.

The ORA Office of Regulatory Science will maintain and update lists detailing the expansion of food matrices for methods used by ORA laboratories; these lists will be posted on the ORA Office of Regulatory Science website.

### 5.1.2 Matrix Extension Guidance for New Foods From a Different Category Than That Used for the Original Method Validation Study

In instances where a method will be used to test a food (or foods) for which it has not previously been validated *and* the food (or foods) is not within the same category of food (See APPENDIX 5) included in the original validation study, then an independent validation study will be required as described in Table 1.

## 5.2 Platform Extension

Platform extension refers to the proposed use of a new, similarly functioning instrument into approved method that *differs* from the one used in the original validation study. Such platform differences may include (but not be limited to) being of similar function and capacity but from a different manufacturer; from the same manufacturer but with significantly different performance parameters (i.e. capacity, capabilities); or, represent the next generation for that type of instrumentation to include newer technology and/or reagent reformulations.

The use of specialized instrumentation (and in many cases their accompanying proprietary reagents) dictate the performance standards of validated analytical methods. Therefore, it cannot be assumed that the impact on the method's performance from any interchangeability of instrumentation will be negligible. Performance comparability must be assessed.

In general, platform extension validation must be done by comparing the proposed new platform to the previously validated platform. The scope of the validation study may vary from case to case and will be dependent on such factors as reformulation of buffers, primers, probes, alternative proprietary chemistries, threshold of detection sensitivity, etc. Each case will be judged independently through examination of publicly accessible data, input from SMEs, the method developer, and the MMVS.

In planning platform extension validation, the method developer and the MMVS, must determine what aspect of the technology will be compared in order to determine how the study should proceed. In some instances a platform extension study may require only a simple verification process. Other instances, however, may necessitate an SLV or Independent Validation Study as described in Table 1.

# APPENDIX 1
# Glossary of Terms

**Action level:** Level of concern for an analyte that must be reliably detected, identified or quantified in a sample.

**Accuracy:** A measure of the degree of conformity of a value generated by a specific procedure to the assumed or accepted true value, and includes precision and bias.

**Alternate method:** The newly developed or modified method that is to be evaluated against the performance of a recognized reference method by a defined validation process.

**Analytical batch:** An analytical batch consists of samples which are analyzed together with the same method sequence and same lots of reagents and with the manipulations common to each sample within the same time period or in continuous sequential time periods. A set of measurements or test results taken under conditions that do not vary within a 24 hour time period.

**Analyte:** Component measured by the method of analysis. In the case of microbiological methods, it is the microorganism or associated by-products (e.g., enzymes or toxins).

**Applicability:** The analytical purpose for which a method has been validated.

**Bias:** The difference between the expectation of the test results and an accepted reference value.

> **NOTE:** *Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias. A larger systematic error difference from the accepted reference value is reflected by a larger bias value.*

**Calibration:** The set of operations which establish, under specific conditions, the relationship between values of quantities by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

**Certified Reference Material (CRM):** Reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes metrological traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence (slightly modified from VIM04)

> **NOTE:** *The term "Standard Reference Material" (SRM) is the name of a certified reference material (CRM), which is the trademark name of a*

*certified reference material that has been certified and is distributed by the National Institute of Standards and Technology (NIST).*

**Collaborative study:** A Collaborative study is an inter-laboratory study in which each laboratory uses the defined method of analysis to analyze identical portions of homogeneous materials to assess the performance characteristics obtained for that method of analysis. It is designed to measure inter-laboratory reproducibility, so that it can be determined if the method can be successfully performed by laboratories other than the originating laboratory. For methods having more than one sample preparation or enrichment scheme, it is necessary to test one matrix per sample preparation or enrichment scheme.

**Detection limit:** A detection limit is the lowest amount of analyte in a sample which can be detected but, not necessarily quantified, as an exact value. It is often called the limit of detection (LOD), which is the lowest concentration level that can be determined as statistically different from a blank at a specified level of confidence. It is determined from the analysis of sample blanks and samples at levels near the expected LOD (see ISO 11843, CLSI EP17).

**Exclusivity:** Specificity; the ability of the method to distinguish the target from similar but genetically distinct non-target. It is the lack of interference in the alternative method from a relevant range of non-target strains, which are potentially cross-reactive.

**Food category:** A group of specific related foods. Appendix 2 lists nine recommended food categories: meat products, poultry, fish and seafood products, fruit- and vegetable-based products, dairy products, chocolate/bakery products, animal feeds, pasta, and miscellaneous.

**Food matrix:** Components that comprise the food sample.

**Food product:** Any substance usually composed primarily of carbohydrates, fats, water and/or proteins that can be eaten or drunk by an animal or human for nutrition or pleasure. See APPENDIX 5 for examples of representative food products.

**Food type:** An item that is processed, partially processed or unprocessed for consumption. APPENDIX 5 lists various types such as raw, heat processed, frozen, fermented, cured, smoked, dry, low moisture, etc.

**Fractional recovery:** Validation criterion that is satisfied when a common set of samples (e.g., inoculation level), yields a partial number of positive determinations and a partial number of negative determinations within a replicate set of samples. The proportion of positive samples should approximate 50% (±25%) of the total number of replicates in the set. A set of replicate analyses are those replicates analyzed by on method (either reference or alternate). In the context of the entire data set, values outside the prescribed

fractional range (50%±25%) may be considered. For example, for studies where a larger number of test portions were analyzed, (i.e., 60), a larger fractional range may be acceptable. Other parameters may be considered on an individual basis.

**Inclusivity:** Sensitivity; the ability of the method to detect a wide range of targets by a defined relatedness e.g. taxonomic, immunological, genetic composition.

**Incurred samples:** Naturally-contaminated test samples.

**Laboratory:** An entity that performs tests and/or calibrations. When a laboratory is part of an organization that carries out activities additional to sample preparation, testing and calibration, the term laboratory refers only to those parts of that organization that are involved in the sample preparation, testing and calibration process. A laboratory's activities may be carried out at a permanent, temporary, or remote location.

**Limit of Quantification (LOQ):** Lowest amount or concentration of analyte that can be quantitatively determined with an acceptable level of uncertainty, also referred to as the limit of determination.

**Linearity:** Defines the ability of the method to obtain test results proportional to the concentration.

**Matrix blank:** A quality control sample of a specified amount of matrix that does not contain the analyte of interest.

**Matrix spike:** An aliquot of a sample prepared by adding a known quantity of target analytes to a specified amount of matrix and subjected to the entire analytical procedure to establish if the method or procedure is appropriate for the analysis of a specific analyte in a particular matrix.

**Method blank:** Quality control sample that does not contain the analytes of interest but is subjected to all sample processing operations including all reagents used to analyze the test samples.

**Method Detection Limit (MDL; also known as LOD):** Lowest amount or concentration of analyte that a specific method can statistically differentiate from analyte-free sample matrix. This is dependent on sensitivity, instrumental noise, blank variability, sample matrix variability, and dilution factor.

**Minimum Detectable Concentration (MDC):** An estimate of the minimum true concentration of analyte that must be present in a sample to ensure a specified high probability (usually >95%) that the measured response will exceed the detection threshold (i.e., critical value), leading one to conclude correctly that the analyte is present.

**Minimum Quantifiable Concentration (MQC)**: The smallest concentration of analyte whose presence in a laboratory sample ensures the relative standard deviation of the measurement does not exceed a specified value, usually 10 percent.

**Precision:** Degree of agreement of measurements under specified conditions. The precision is described by statistical methods such as a standard deviation or confidence limit. See also Random Error. Repeatability expresses the precision under the same operating conditions over a short period of time. Intermediate precision expresses within-laboratory variations, such as different days, different analysts, and different equipment. Reproducibility expresses the precision between laboratories.

**Qualitative method:** A method that identifies analyte(s) based on chemical, biological, or physical properties; method of analysis whose response is either the presence or absence of the analyte detected either directly or indirectly in a certain amount of sample. Most qualitative methods are or can be made at least "semi-quantitative" to provide rough estimates of the amount of analyte present.

**Quantifiable method:** A method that provides an estimate of the amount of analyte present in the test sample, expressed as a numerical value in appropriate units, with trueness and precision which are fit for the purpose.

**Random error:** The irreproducibility in making replicate measurements resulting from random changes in experimental conditions that affects the precision of a result. The distribution of random errors usually follows a Gaussian bell-shaped curve. See also Precision.

**Range:** The interval of concentration over which the method provides suitable precision and accuracy.

**Recovery:** Proportion of incurred or added analyte which is extracted and measured from the analytical portion of the test sample.

**Reference material:** A material or substance, one or more of whose property values are sufficiently homogenous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

**Reference standard:** A standard, generally having the highest metrological quality available at a given location in a given organization, from which measurements are made or derived. Note: Generally, this refers to recognized national or international traceable standards provided by a standards producing body such as the National Institute of Standards and Technology (NIST).

**Relative Limit of Detection:** The limit of detection of the alternate method divided by the limit of detection of the reference method.

**Repeatability:** The closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement.

**Ruggedness or robustness:** The ability of a method to resist changes in test results when subjected to minor deviations in experimental conditions of the procedure. Ruggedness testing examines the behavior of an analytical process when subtle small changes in the environment and/or operating conditions are made, akin to those likely to arise in different test environments.

**Screening method:** A method intended to detect the presence of an analyte in a sample at or above some specified concentration (target level).

**Specificity:** The capability of a method to discriminate between the analyte of interest and other components of the sample including matrix components.

**Sensitivity:** The lowest concentration that can be distinguished from background noise or the smallest amount of a substance or organism that can accurately be measured by a method or test system is the analytical sensitivity. However, sensitivity is commonly defined as the slope of the calibration curve at a level near the LOQ.

**Source:** The origin of a test sample. A sample matrix may have variability due to its source. For example, a water sample may have variable characteristics, and therefore, may show method results variability, depending on whether the sample source is drinking water, ground water, surface water, or waste water.

> [a] Different food sources are defined as different commercial brands. Different water sources could be from different areas of a reservoir. Different plant or soil sources could be samples from the different areas of a plot or field. Different sediment sources could be samples from different areas of a water body.
>
> **NOTE:** The number of sources for a food method validation study may be determined by the number and selection of matrices analyzed in the method validation study. For example, if a variety of food matrices with differing physical and chemical properties are selected, the number of sources for each food sample matrix may be one or more. For a method validation study analyzing one food matrix, 3-5 sources of the food matrix are recommended.

**Specificity**: Analytical specificity is the ability of a method to measure one particular analyte in the presence of components which may be expected to be present.

**Standard Reference Material (SRM):** A certified reference material issued by the National Institutes of Standards and Technology (NIST) in the United States. An SRM is certified by NIST for specific chemical or physical properties and is issued with a certificate that reports the results of the characterization and indicates the intended use of the material (www.nist.gov/SRM).

**Strain:** A group of microorganisms of the same species having distinctive hereditary characteristics not typical of the entire species; a subset of a bacterial species differing from other bacteria of the same species by minor but identifiable differences

**Systematic error:** A form of measurement error, where error is constant across trials. This may also be referred to as Bias.

**Target level:** The level at which an analyte can be reliably identified or quantified in a sample.

**Trueness:** The degree of agreement of the expected value from a measurement with the true value or accepted reference value. This is related to systematic error (bias).

**Uncertainty:** The parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand. (VIM, 1993)

**Validation, method:** The confirmation by examination and the provision of objective evidence that the particular requirements for the specific use of a method are fulfilled.

**Validation of an alternative method:** Demonstration that adequate confidence is provided when the results obtained by the alternative method are comparable to those obtained using the reference method using the statistical criteria contained in the approved validation protocol.

**Verification:** The confirmation by examination and provision of the objective evidence that specified requirements for the performance of a method have been fulfilled by an individual laboratory. Also, the means used to demonstrate that the method functions (without any adaptation) in the user's laboratory on matrices not included in the original method validation.

# APPENDIX 2
# SRSC Method Validation Subcommittee Charter

SRSC Method
Validation Subcommit

# APPENDIX 3
## Method Development, Validation and Implementation SOP

Methods
Development-Validatio

# APPENDIX 4
# FVM Microbiology Method Validation Study Application

FVM Micro Method
Validation Study Appli

# APPENDIX 5

## Examples of Food Types and Associated Microbiological Contaminants

### Table 1-Food Categories Relevant to Foodborne Pathogenic Bacteria

*(AOAC Classification of Food Categories, Feldsine et al., (2002) JAOACI 85(5) 1197 – 1198)*

| Food type | Yersinia | Clostridium perfringens | Listeria mono | E. coli O157 | Staph aureus | Campy | Salmonella | B. cereus |
|---|---|---|---|---|---|---|---|---|
| **Meats** | | | | | | | | |
| raw | x | | x | x | | X | x | x |
| heat processed | | | x | x | x | | x | |
| frozen | | | x | x | | | x | |
| fermented | | | x | x | | | x | |
| cured | | x | x | | x | | x | |
| other | | dishes / gravy | pate | | | | | |
| **Poultry** | | | | | | | | |
| raw | x | | | | | X | x | |
| heat processed | | | | | | | x | |
| frozen | | | | | | | x | |
| other | | dishes / gravy | | | | | | |
| **Seafood** | | | | | | | | |
| raw | x | | x | x | | X | x | |
| heat processed | | | | | | | x | |
| frozen | | | x | x | | | x | |
| shellfish | x | | | x | | X | x | |
| smoked | | x | x | | x | | x | |
| other | | | | | | | x | |
| **Fruits & Vegetables** | | | | | | | | |
| unpasteurized juice | | | | x | | | x | |
| raw | x | | x | x | | X | x | |
| heat processed | | x | | | | | | |
| frozen | | | x | | | | x | |
| dry | | | | | | | | x |
| juice/concentrate | | | | x | | | x | |
| low moist | | | | | | | x | |
| nut meats | | | x | x | | | x | |
| others | | | | | | | | |
| **Dairy** | | | | | | | | |
| raw | x | | x | x | x | X | x | x |
| heat processed | | | x | | | | | x |
| frozen | | | x | x | x | | x | x |
| Fermented? | | | x | x | x | | x | |
| dry | | | | | x | | x | x |
| ice cream | | | x | | | | x | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| cheese | | | x | x | | | x | |
| **Chocolate / bakery** | | | | | | | | |
| low moist | | | | | | | x | |
| dry powder | | | | | | | x | |
| milk chocolate | | | | | | | x | |
| other | | | | | pastry | | | custard |
| **Animal feed** | | | | | | | | |
| low moist | | | | | | | x | |
| pet food | | | | | | | x | |
| **Pasta** | | | | | | | | |
| uncooked | | | | | | | x | |
| **Misc** | | | | | | | | |
| dressings | | | x | x | | | x | |
| spices | | x | | | | | x | |
| mayonnaise | | | x | x | | X | x | |
| flour | | | x | | | X | x | |
| egg / derivatives | | | | x | | | x | |
| cereal/rice | | | | | | | | x |

Table 2 - AOAC Food Categories Relevant to Non-pathogenic Microorganisms

| Product | Yeast & Mold | Lactics | Total Viable | Coliform | E. coli |
|---|---|---|---|---|---|
| **Meat** | | | | | |
| raw | x | x | x | X | x |
| heat processed | | x | x | X | |
| frozen | x | | x | X | x |
| Fermented | x | x | x | | |
| cured | | x | x | | |
| **Poultry** | | | | | |
| raw | x | x | x | X | x |
| heat processed | | x | x | X | |
| frozen | x | | x | X | x |
| other | | | x | | |
| **Seafood** | | | | | |
| raw | x | x | x | X | x |
| heat processed | | x | x | X | |
| frozen | x | | x | X | x |
| smoked | x | x | x | X | |
| **Fruits & Vegetables** | | | | | |
| raw | x | x | x | X | x |
| heat processed | | | x | X | |
| frozen | x | | x | X | |
| dry | x | | x | X | |
| fermented | x | | x | | |
| cured/salted | x | | x | | |
| juice/concentrate | x | x | x | | |
| low moist | x | | x | | |
| **Dairy** | | | | | |
| raw | x | x | x | X | x |
| heat processed | | | x | X | |
| frozen | x | | x | X | x |
| Fermented | x | | | | x |
| dry | | | x | X | |
| **Choc/bakery** | | | | | |
| low moist / IMF | x | | x | X | |
| dry | | | x | X | |
| milk chocolate | x | | x | X | |
| **Animal feed** | | | | | |
| low moist | x | | x | X | |
| dry pet | x | | x | X | x |
| **Pasta** | | | | | |
| uncooked | x | | x | X | |
| **Misc** | | | | | |
| dressings | x | x | x | X | x |
| spices | | | x | | x |
| mayonnaise | x | x | x | | x |
| egg / derivatives | | | x | X | |

| | | | | | |
|---|---|---|---|---|---|
| cereal / rice | | | x | X | |

## Representative Food Products in Categories

**Meats:**
Ground beef, ground pork, meat by-products, glandular products, frog legs, rabbit carcasses, lamb, sausage, frankfurters, lunch meat, beef jerky, meat substitutes

**Poultry:**
Ground chicken, ground turkey, cooked chicken, raw chicken parts

**Seafood:**
Raw shrimp, fish sticks, surimi, raw fish filet, raw oysters, raw mussels, raw clams, cooked crawfish, smoked fish, pasteurized crabmeat

**Fruits & Vegetables:**
Fresh / frozen fruits or dried fruits, orange juice, apple juice, apple cider, tomato juice, melon cubes, berries
Pecans, walnuts, peanut butter, coconut, almonds
Lettuce, spinach, kale, collard greens, cabbage, bean sprouts, seed sprouts, spent water from sprouts, peas, mushroom, green beans

**Dairy:**
Yogurt, cottage cheese, hard and soft cheeses, raw or pasteurized liquid milk (skim, 2% fat, whole, buttermilk), infant formula, coffee creamer, ice cream, nonfat dry milk / dry whole milk, dried buttermilk, dried cheese spray

**Chocolate / bakery:**
Frosting and topping mixes, candy and candy coating, milk chocolate

**Animal feed:**
Dry pet food, meat and bone meal, chicken and feather meal

**Uncooked Pasta:**
Uncooked noodles, macaroni, spaghetti

**Miscellaneous:**
Shell eggs, liquid whole eggs, oral or tube feedings containing egg, dried whole egg or dried egg yolk, dried egg whites
Oregano, pepper, paprika, black pepper, white pepper, celery seed or flakes, chili powder, cumin, parsley flakes, rosemary, sesame seed, thyme, vegetable flakes, onion flakes, onion powder, garlic flakes, allspice
Wheat flour, casein, cake mixes, whey, nonfat dry milk/dry whole milk, corn meal, dried whole egg or dried egg yolk, dried egg whites, soy flour, dried yeast, cereals, dried buttermilk, dry cheese spray

# APPENDIX 6
## Strains and Serovars for Inclusivity and Exclusivity Panels
*(abridged)*

- This appendix is meant to serve as a guide or starting point for the method developer as they construct exclusive and inclusive panels for method validation and is not intended to be exhaustive.
- Access to microbial analyte strain and serovar and collections within the FVM research enterprise is governed by "U.S. Food and Drug Administration Foods Program Internal Strain Sharing Standard Operating Procedure"

| | Serotype | Genotype | | |
|---|---|---|---|---|
| | | *stx*1 | *stx*2 | *uid*A-O157:H7/H- |
| **EHEC** | O157:H7 | + | + | + |
| | O157:H7 | + | - | + |
| | O157:H7 | - | + | + |
| | O157:H7 | - | - | + |
| | O157:H- | + | + | + |
| | O157:H- | - | + | + |
| **STEC** | O68:H- | + | + | - |
| | O48: | | | |
| | O45:H2 | | | |
| | O137:H41 | | | |
| | O111:H- | | | |
| | O22:H8 | | | |
| | O15:H27 | | | |
| | O4:H- | | | |
| | O26:H11 | + | - | - |
| | O26:H- | | | |
| | O45:H2 | | | |
| | O85:H- | | | |
| | O103:H2 | | | |
| | O103:H6 | | | |
| | O111:H11 | | | |
| | O125:H- | | | |
| | O126:H27 | | | |
| | O146:H21 | | | |
| | *E coli, stx*1 Insert | | | |
| | O14:H19 | - | + | - |
| | O28:H35 | | | |
| | O48:H21 | | | |
| | O55:H7 | | | |
| | O104:H21 | | | |
| | O121:H19 | | | |
| | O165:H25 | | | |
| | *E. coli, stx*2 Insert | | | |
| **Non-toxigenic *E. coli*** | Non-O157:H7 | - | - | - |
| | O55:H7 | | | |
| | O157:H16 | | | |

O157:H45

I. *E.*

*coli O157:H7*

| | Serotype | Genotype | | |
|---|---|---|---|---|
| | | *stx*1 | *stx*2 | *uid*A-O157:H7/H- |
| *Shigella dysenteriae* | | + | - | - |
| *Hafnia alvei* | | - | - | - |
| *Morganella morganii* | | - | - | - |
| *Citrobacter fruendii* | | - | - | - |
| *Lectercia adecarboxylata* | | - | - | - |
| *Hafnia alvei* | | - | - | - |
| *Shigella sonnei* | | - | - | - |
| *Shigella boydii* | | - | - | - |
| *Shigella flexneri* | | - | - | - |
| *Citrobacter fruendii* | | - | - | - |
| *Salmonella* Grp. 30 | | - | - | - |
| *Salmonella lansing Grp.P* | | - | - | - |
| *Klebsiella pneumoniae* | | - | - | - |
| *Listeria monocytogenes* | | - | - | - |
| *Listeria innocua* | | - | - | - |
| *Listeria ivanovii* | | - | - | - |
| *Listeria seeligeri* | | - | - | - |
| *Listeria welshimeri* | | - | - | - |
| *Vibrio cholerae* | O1 Inaba | - | - | - |
| *Vibrio parahaemolyticus* | O4 | - | - | - |
| *Vibrio vulnificus* | | - | - | - |
| *Staphylococcus aureus* | | - | - | - |
| *Rhodococcus equi* | | - | - | - |
| *Lactobacillus* sp. | | - | - | - |
| *Lactobacillus* sp. | | - | - | - |
| *Salmonella typhimurium* | | - | - | - |
| *Streptococcus pyogenes* | | - | - | - |
| *Algaligenes faecalis* | | - | - | - |
| *Salmonella choleraesuis* | | - | - | - |
| *Yersinia entercolitica* | | - | - | - |
| *Yersinia entercolitica* | | - | - | - |
| *Enterobacter cloacae* | | - | - | - |

## II. *Salmonella* (inclusivity)

Note: (Derived from the Defense Science Office (DSO) of the Defense Advance Research Projects Agency (DARPA) Systems and Assays for Food Examination (SAFE) Program.

### IIa. *Salmonella*: Subspecies Set

| SAFE Designation | Original Designation | Serotype | Subsp. |
|---|---|---|---|
| 1 | 02-0061 | Newport | I |
| 2 | 02-0062 | Enteritidis | I |
| 3 | 02-0105 | Heidelberg | I |
| 4 | 02-0115 | Typhimurium | I |
| 5 | 2433 | Typhi | I |
| 6 | CNM-1029/02 | 4,5,12:b:- | I |
| 7 | CNM-3578/03 | Hadar | I |
| 8 | CNM-3663/03 | Virchow | I |
| 9 | CNM-3685/03 | Brandenburg | I |
| 10 | 00-0163 | II 58:l,z13,z28:z6 | II |
| 11 | 00-0324 | II 47:d:z39 | II |
| 12 | 01-0227 | II 48:d:z6 | II |
| 13 | 01-0249 | II 50:b:z6 | II |
| 14 | CNM-169 | II 53:lz28:z39 | II |
| 15 | CNM-176 | II 39:lz28:enx | II |
| 16 | CNM-4290/02 | II 13,22:z29:enx | II |
| 17 | CNM-466/03 | II 4,12:b:- | II |
| 18 | CNM-5936/02 | II 18:z4,z23:- | II |
| 19 | 01-0089 | IIIa 41:z4,z23:- | IIIa |
| 20 | 01-0204 | IIIa 40:z4,z23:- | IIIa |
| 21 | 01-0324 | IIIa 48:g,z51:- | IIIa |
| 22 | 02-0111 | IIIa 21:g,z51:- | IIIa |
| 23 | CNM-247 | IIIa 51:gz51:- | IIIa |
| 24 | CNM-259 | IIIa 62:g,z51:- | IIIa |
| 25 | CNM-3527/02 | IIIa 48:z4,z23,z32:- | IIIa |
| 26 | CNM-7302/02 | IIIa 48:z4,z23:- | IIIa |
| 27 | 01-0170 | IIIb 60:r:e,n,x,z15 | IIIb |
| 28 | 01-0221 | IIIb 48:i:z | IIIb |
| 29 | 01-0248 | IIIb 61:k:1,5,(7) | IIIb |
| 30 | 02-0188 | IIIb 61:l,v:1,5,7 | IIIb |
| 31 | CNM-3511/02 | IIIb 48: z10: e,n,x,z15 | IIIb |
| 32 | CNM-4190/02 | IIIb 38:z10:z53 | IIIb |
| 33 | CNM-750/02 | IIIb 60:r:z | IIIb |
| 34 | CNM-834/02 | IIIb 50:i:z | IIIb |
| 35 | 01-0133 | IV 50:g,z51:- | IV |
| 36 | 01-0147 | IV 48:g,z51:- | IV |
| 37 | 01-0149 | IV 44:z4,z23:- | IV |
| 38 | 01-0276 | IV 45:g,z51:- | IV |
| 39 | 01-0551 | IV 16:z4,z32:- | IV |
| 40 | CNM-1904/03 | IV 11:z4,z23:- | IV |
| 41 | CNM-4708/03 | IV 6,7:z36:- | IV |

| | | | |
|---|---|---|---|
| 42 | ST-16 | IV 16:z4,z32:- | IV |
| 43 | ST-21 | IV 40:g,z51:- | VII |
| 44 | ST-22 | IV 40:z4,z24:- | VII |
| 45 | 94-0708 | V 48:i:- | S. bongori |
| 46 | 95-0123 | V 40:z35:- | S. bongori |
| 47 | 96-0233 | V 44:z39:- | S. bongori |
| 48 | CNM-256 | V 60:z41:- | S. bongori |
| 49 | CNM-262 | V 66:z41:- | S. bongori |
| 50 | 95-0321 | V 48:z35:- | S. bongori |
| 51 | 1121 | VI 6,14,25:z10:1,(2),7 | VI |
| 52 | 1415 | VI 11:b:1,7 | VI |
| 53 | 1937 | VI 6,7:z41:1,7 | VI |
| 54 | 2229 | VI 11:a:1,5 | VI |
| 55 | 811 | VI 6,14,25:a:e,n,x | VI |

**IIb. *Salmonella*: Outbreak Cluster Set**

| SAFE Designation | Original Designation | Serotype |
|---|---|---|
| 56 | AM04695 | Typhimurium / DT' 04b |
| 57 | K0507 | Typhimurium |
| 58 | H8289 | Typhimurium |
| 59 | H8290 | Typhimurium |
| 60 | H8292 | Typhimurium |
| 61 | H8293 | Typhimurium |
| 62 | H8294 | Typhimurium |
| 63 | 2009K0191 | Typhimurium |
| 64 | 2009K0208 | Typhimurium |
| 65 | 2009K0224 | Typhimurium |
| 66 | 2009K0226 | Typhimurium |
| 67 | 2009K0230 | Typhimurium |
| 68 | 2009K0234 | Typhimurium |
| 69 | 2009K0350 | Typhimurium |
| 70 | AM03380 | Typhimurium / DT 104 |
| 71 | AM01797 | Typhimurium / DT 104 |
| 72 | AM03759 | Typhimurium / DT 104 |
| 73 | CDC_07-0708 | I 4,[5],12:i:- |
| 74 | CDC_08-0061 | I 4,[5],12:i:- |
| 75 | CDC_08-0134 | I 4,[5],12:i:- |
| 76 | CDC_07-835 | I 4,[5],12:i:- |
| 77 | CDC_07-934 | I 4,[5],12:i:- |
| 78 | CDC_07-922 | I 4,[5],12:i:- |
| 79 | CDC_07ST000857 | Enteritidis |
| 80 | CDC_08-0253 | Enteritidis |
| 81 | CDC_08-0254 | Enteritidis |

**IIc. *Salmonella*: Food Set**

| SAFE Designation | Original Designation | Serotype |
|---|---|---|
| 82 | 2105 H | Saphra |
| 83 | 1465 H | Rubislaw |
| 84 | 2069 H | Michigan |
| 85 | 2308 H | Urbana |
| 86 | 885 H | *Vietnam* |
| 87 | 3030 H | *Tornow* |
| 88 | 768 H | *Gera* |
| 89 | 1941 H | *Fresno* |
| 90 | 3029 H | *Brisbane* |
| 91 | 4000 H | *Agona* |
| 92 | 1501 H | *Muenchen* |
| 93 | 1097 H | *Senftenberg* |
| 94 | 1250 H | *Muenster* |
| 95 | 1 H | *Montevideo* |
| 96 | 1070 H | *Johannesburg* |
| 97 | 2080 H | *Javiana* |
| 98 | 3170 H | *Inverness* |
| 99 | 1061 H | *Cubana* |
| 100 | 1158 H | *Cerro* |
| 101 | 1988 H | *Alachua* |

## III. *Listeria spp.*

| Organism | Isolate # | Isolate Information | Serology |
|---|---|---|---|
| | | **Food Isolates** | |
| *L. monocytogenes* | 15b42 | cucumber | 4 |
| | 3365 | mackerel | 4b6 |
| | 3312 | cheese | 1a1 |
| | 15b27 | radish | 1 |
| | 2388 | coleslaw | 1 |
| | 2478 | raw milk | 1 |
| | 3313 | shrimp | 1a1 |
| | 3326 | roast beef | 1a1 |
| | 3358 | milk product | 1a2 |
| | 3363 | cook snow crab | 1a2 |
| | 3756 | beef & gravy Rh- | 1 |
| | 15b72 | apple juice | 1 |
| | 15b85 | cream ch. & veg | 1 |
| | 15c14 | avocado pulp | 1 |
| | 15c22 | fontina cheese | 1 |
| | 15a90 | turkey ham | 3b |
| | 2450 | veg. mix | 1 |
| | 2475 | cold cut sand. | 1 |
| | 2492 | ice cream | 1 |
| | 3291 | popsicle | 1a1 |
| | 3318 | lobster | 1a2 |
| | 3321 | raw shrimp | 4b6 |
| | 3332 | mex-style cheese | 4b6 |
| | 3359 | surimi scallops | 1a1 |
| | 3362 | Pollack | 1a1 |
| | 3558 | cheese | 4b |
| | 3644 | red bean ice bar | 4b6 |
| | 3662 | cheese | 4b6 |
| | 15b70 | cheddar cheese | 4 |
| *L. monocytogenes* | 2369 | **Patient Isolates** | 1 |
| | 2370 | | 1 |
| | 15b55 | | 1 |
| | 15b66 | | 1 |
| | 3555 | | 4 |
| | 3664 | | 1a1 |
| | 3666 | | 4b6 |
| | 3668 | | 4b6 |
| | 15a82 | | 4 |
| | 15b56 | | 4 |
| | 15b58 | | 4 |
| | 15b81 | | 1 |
| | 15b82 | | 4 |
| *L. monocytogenes* | 3315 | **Environmental Isolates (swab)** | 1a1 |
| | 3286 | | 1a2 |
| | 3308 | | 1a2 |

| | | | |
|---|---|---|---|
| | 3360 | | 1a1 |
| *L. monocytogenes* | KC 1710 | Other Isolates | 4a7,9 |
| | ATCC 19114 | | 4a |
| | V-7 | | 1a1 |
| | ATCC 15313 | | 1 |
| | Scott A | | 4b6 |
| | ATCC 19116 | | 4c |
| | ATCC 19115 | | |

| Organism | Isolate # | Organism | Isolate # |
|---|---|---|---|
| *L. innocua* | 3107 | L. welshimeri | 2230 |
| | 3124 | | 2231 |
| | 3516 | | 3425 |
| | 3654 | | 3441 |
| | 3758 | | 3659 |
| | 6273 | | 15b05 |
| | 3181 | | 15b06 |
| | 3270 | | 15b16 |
| | 3390 | | 15b46 |
| | 3392 | | 15b48 |
| | 3552 | | 15b50 |
| | 3757 | Hafnia alvei | 6410 |
| | 15a93 | E. coli | 6365 |
| | 15a94 | Morganella morganii | 13b67 |
| | 15a95 | Shigella dysenteriae | 13c94 |
| | 15b30 | Citrobacter freundii | 13d26 |
| | 15b31 | E. coli | 13d64 |
| | 15b51 | Leclercia adecarboxylata | 13d65 |
| | 15a92 | Hafnia alvei | 13d66 |
| | ATCC 33090 | Shigella sonnei | 13g01 |
| *L. ivanovii* | 2244 | Shigella boydii | 13g18 |
| | 3106 | Shigella flexneri | 13g19 |
| | 3417 | Citrobacter freundii | 6251 |
| | 6274 | Salmonella Grp. 30 | 6269 |
| L. ivanovii | 15a96 | Salmonella lansing Grp. P | 6270 |
| | 15a97 | Klebsiella pneumonia | 6271 |
| | 15a98 | Vibrio cholerae | 6277 |
| | 15b24 | Vibrio parahaemolyticus | 6278 |
| | ATCC 19119 | Vibrio vulnificus | 6279 |
| L. seeligeri | 2232 | Staphylococcus aureus | ATCC 25923 |
| | 2233 | Rhodococcus equi | 6281 |
| | 2243 | Lactobacillus sp. | 6282 |
| | 2302 | Lactobacillus sp. | 6286 |
| | 3110 | Salmonella typhimurium | 6290 |
| | 3126 | Streptococcus pyogenes | ATCC 19615 |
| | 3389 | Alcaligenes faecalis | ATCC 8750 |
| | 3423 | Salmonella choleraesuis | ATCC 6539 |
| | 3439 | Yersinia entercolitica | 1269 |

| | | | |
|---|---|---|---|
| L. seeligeri *(continued)* | 3451 | Yersinia entercolitica | 1270 |
| | 3517 | E. coli | 13a80 |
| | 3531 | Enterobacter cloacae | 18g53 |
| | 3656 | | |
| | 6275 | | |
| | 15b07 | | |
| | 15b08 | | |
| | 15b09 | | |
| | 15b26 | | |
| | 15b28 | | |
| | 15b49 | | |

# IV. *Shigella*

**Inclusive Panel**

| Genus | Species (Group) | Serotype |
|---|---|---|
| *Escherichia* | *Escherichia coli*, Enteroinvasive | |
| *Shigella* | Provisional | Unknown |
| *Shigella* | *bodyii* (C) | 1 |
| | | 2 |
| | | 3 |
| | | 4 |
| | | 5 |
| | | 6 |
| | | 7 |
| | | 8 |
| | | 9 |
| | | 10 |
| | | 11 |
| | | 12 |
| | | 13 |
| | | 14 |
| | | 15 |
| | | 16 |
| | | 17 |
| | | 18 |
| *Shigella* | *dysenteriae* (A) | 1 |
| | | 2 |
| | | 3 |
| | | 4 |
| | | 5 |
| | | 6 |
| | | 7 |
| | | 8 |
| | | 9 |
| | | 10 |
| | | 11 |
| | | 12 |
| | | 13 |
| | | 14 |
| | | 15 |
| *Shigella* | *flexneri* (B) | 1 |
| | | 1a |
| | | 1b |
| | | 2 |
| | | 2a |
| | | 2b |
| | | 3 |
| | | 3a |
| | | 3c |
| | | 4 |
| | | 4a |
| | | 5 |
| | | 5a |
| | | 5b |
| | | 6 |
| *Shigella* | *flexneri*, provisional (B) | Unknown |
| *Shigella* | *sonnei* (D) | |

## IV. *Shigella* (continued)

| Bacteria strain | Strain no. | Source* |
|---|---|---|
| *Acinetobacter baumannii* | 19606 | ATCC |
| *Aeromonas caviae* | 15468 | ATCC |
| *Aeromonas hydrophila* | 7966 | ATCC |
| *Bacillus licheniformis* | 12759 | ATCC |
| *Bacillus sphaericus* | 4525 | ATCC |
| *Bacillus stearothermophilus* | 12016 | ATCC |
| *Bacillus subtilis* | 6633 | ATCC |
| *Bordetella bronchiseptica* | 10580 | ATCC |
| *Burkholderia cepacia* | 25608 | ATCC |
| *Citrobacter freundii* | 255 | PRLSW |
| *Citrobacter freundii* | food isolate | PRLSW |
| *Citrobacter freundii* | 68 | MNDAL |
| *Citroabcter younger* | food isolate | PRLSW |
| *Clostrodium sporogenes* | 11437 | ATCC |
| *Edwardsiella tarda* | 254 | PRLSW |
| *Enterobacter aerogenes* | 13048 | ATCC |
| *Enterobacter aerogenes* | 11 | VADCLS |
| *Enterobacter cancerogenus* | food isolate | PRLSW |
| *Enterobacter cloacae* | 260 | PRLSW |
| *Enterobacter cloacae* | 71 | MNDAL |
| *Enterococcus durans* | 6056 | ATCC |
| *Enterococcus faecalis* | 7080 | ATCC |
| *Erysipelothrix rhusiopathiae* | 19414 | ATCC |
| Enterotoxgenic *E. coli* | H10407 | CFSAN |
| Enterotoxgenic *E. coli* | C600/pEWD299 | CFSAN |
| Enterotoxgenic *E. coli* | 65 | MNDAL |
| *Escherichai coli* O157:H7 | 43890 | ATCC |
| *Escherichai coli* O157:H7 | 43888 | ATCC |
| *Escherichai coli* O157:H7 | 43895 | ATCC |
| *Escherichai coli* O157:H7 | 68-98 | CDC |
| *Escherichai coli* O157:H7 | 24-98 | CDC |
| *Escherichai coli* O157:H7 | 20-98 | CDC |
| *Escherichai coli* O157:H7 | 16-98 | CDC |
| *Escherichai coli* O157:H7 | 63 | MNDAL |
| *Escherichai coli* O157:H7 | 4 | VADCLS |
| *Escherichai coli* O157:H44 | 26 | VADCLS |
| *Escherichia coli* O111:NM | 04.SB.00067 | OCPHL |
| *Escherichia coli* O143:H4 | 05.SB.00141 | OCPHL |
| *Escherichia coli* | 8739 | ATCC |
| *Escherichia coli* | 25922 | ATCC |
| *Escherichia coli* (hemo +) | food isolate | PRLSW |
| *Escherichia coli* (hemo +) | 28 | VADCLS |
| *Escherchia coli* (sorbitol –) | food isolate | PRLSW |
| *Escherchia coli* (sorbitol –) | food isolate | PRLSW |
| *Escherchia coli* | 64 | MNDAL |
| *Escherchia coli* | 74 | MNDAL |
| *Escherichi coli* | 8 | VADCLS |
| *Klebsiella pnenumoniae* | 13883 | ATCC |
| *Klebsiella pnenumoniae* | 75 | MNDAL |
| *Klebsiella oxytoca* | 66 | MNDAL |
| *Leclercia adecarboxylata* | 23216 | ATCC |

| | | |
|---|---|---|
| *Leclercia adecarboxylata* | 73 | MNDAL |
| *Listeria innocua* | 33090 | ATCC |
| *Listeria ivanovii* | 19119 | ATCC |
| *Listeria monocytogenes* | 19115 | ATCC |
| *Listeria monocytogenes* | H2446 | CDC |
| *Listeria monocytogenes* | H8393 | CDC |
| *Listeria monocytogenes* | H8494 | CDC |
| *Listeria monocytogenes* | H8395 | CDC |
| *Listeria seeligeri* | 35967 | ATCC |
| *Morganella morganii* | 257 | PRLSW |
| *Paenibacillus polymyxa* | 7070 | ATCC |
| *Pantoea agglomerans* | food isolate | PRLSW |
| *Pasteurella aerogenes* | 27883 | ATCC |
| *Plesiomonas shigelloides* | 51903 | ATCC |
| *Proteus mirabilis* | 7002 | ATCC |
| *Proteus mirabilis* | food isolate | PRLSW |
| *Proteus kauseri* | 13315 | ATCC |
| *Proteus vulgaris* | 69 | MNDAL |
| *Providencia alcalifaciens* | 51902 | ATCC |
| *Providencia rettgeri* | 76 | MNDAL |
| *Providencia stuartii* | 257 | PRLSW |
| *Pseudomonas aeruginosa* | 27853 | ATCC |
| *Pseudomonas aeruginosa* | 9027 | ATCC |
| *Pseudomonas aeruginosa* | 67 | MNDAL |
| *Pseudomonas mendocina* | food isolate | PRLSW |
| *Rhodococcus equi* | 6939 | ATCC |
| *Salmonella* Gaminara | 8324 | ATCC |
| *Salmonella diarizonae* | 12325 | ATCC |
| *Salmonella* Abortusequi | 9842 | ATCC |
| *Salmonella diarizonae* | 29934 | ATCC |
| *Salmonella diarizonae* | 252 | PRLSW |
| *Salmonella* Mbandaka | 253 | PRLSW |
| *Salmonella* Tennessee | 249 | PRLSW |
| *Salmonella* Lexington | 248 | PRLSW |
| *Salmonella* Havana | 241 | PRLSW |
| *Salmonella* Baildon | 61-99 | CDC |
| *Salmonella* spp. | 78-99 | CDC |
| *Salmonella* spp. | 87-03 | CDC |
| *Salmonella* spp. | 98-03 | CDC |
| *Salmonella* Braenderup | H 9812 | CDC |
| *Salmonella* Enteritidis | 59 | MNDAL |
| *Salmonella* Heidelberg | 60 | MNDAL |
| *Salmonella* Kentucky | 61 | MNDAL |
| *Salmonella* Newport | 62 | MNDAL |
| *Salmonella* Typhimurium | 30 | VADCLS |
| *Serratia liquefaciens* | 27592 | ATCC |
| *Serratia liquefaciens* | 70 | MNDAL |
| *Sphingomonas paucimobilis* | 72 | MNDAL |
| *Staphylococcus aureus* | 6538 | ATCC |
| *Staphylococcus aureus* | 25923 | ATCC |
| *Staphylococus epidermidis* | 14990 | ATCC |
| *Staphylococcus xylosus* | 29971 | ATCC |
| *Streptococcus equi subsp. equi* | 9528 | ATCC |
| *Streptococcus gallolyticus* | 9809 | ATCC |
| *Streptococcus pyogenes* | 19615 | ATCC |

| | | |
|---|---|---|
| *Vibrio cholerae* | 14035 | ATCC |
| *Vibrio cholerae* | 14033 | ATCC |
| *Vibrio parahaemolyticus* | 17802 | ATCC |
| *Vibrio vulnificus* | 27562 | ATCC |
| *Yersinia enterocolitica* | 51871 | ATCC |
| *Yersinia enterocolitica* | 27729 | ATCC |
| *Yersinia kristensenii* | 33639 | ATCC |

*ATCC: American Type Culture Collection*
*OCPHL: Orange County Public Health Laboratory, CA*
*CDC: Centers for Disease Control and Prevention*
*PRLSW: Pacific Regional Laboratory – Southwest, FDA*
*CFSAN: Center for Food Safety and Applied Nutrition, FDA*
*VADCLS: Virginia Division of Consolidated Laboratory Services*
*MNDAL: Minnesota Department of Agriculture Laboratory*

## V. *Food-borne RNA Viruses*

*These panels were developed and adopted by the FDA BAM council, 200-2008*

### Inclusivity requirements

| Target | Level One | Level Two | Level Three | Level Four |
|---|---|---|---|---|
| Norovirus | 1 Strain Genogroup I<br>1 Strain Genogroup II | 2 Strains - Genogroup I<br>5 Strains - Genogroup II | 5 Strains – Genogroup I<br>10 Strains – Genogroup II | 10 Strains – Genogroup I<br>20 Strains – Genogroup II |
| Hepatitis A | HM175/18f (subgenotype 1B) ATCC #VR-1402 | 5 Strains[a] | 10 Strains[b] | 20 Strains[b] |
| Enterovirus | Poliovirus 1 (attenuated) ATCC #VR-1562 | 5 Strains[c] | 15 Strains[d] | 30 Strains[d] |

### Hepatitis A Panels

**Level Two** (*[a]should include the following strains*):

| | |
|---|---|
| HM175/18f (subgenotype 1B) | ATCC #VR-1402 |
| HAS-15 (subgenotype 1A) | ATCC #VR-2281 |

**Levels Three and Four** (*[b]should include the following strains*):

| | |
|---|---|
| HM175/18f (subgenotype 1B) | ATCC #VR-1402 |
| HAS-15 (subgenotype 1A); | ATCC #VR-2281 |
| LSH/S | ATCC #VR-2266 |
| PA219 (subgenotype IIIA) | ATCC #VR-1357 |

### Enterovirus Panels

**Level Two** (*[c]should include the following strains*):

| | |
|---|---|
| Poliovirus 1 (attenuated) | ATCC #VR-1562 |
| Coxsackievirus A3 | ATCC #VR-1007 |
| Echovirus 1 | ATCC #VR-1038 |

**Levels Three and Four** (*[d]should include the following strains*):

| | |
|---|---|
| Poliovirus 1 (attenuated) | ATCC #VR-1562 |
| Poliovirus 3 (attenuated) | ATCC #VR-63 |
| Coxsackievirus A3 | ATCC #VR-1007 |
| Echovirus 1 | ATCC #VR-1038 |
| Echovirus 21 | ATCC #VR-51 |

## V. *Food-borne RNA Viruses:* *(continued)*

### Exclusivity Panel

| Target | Level One | Level Two | Level Three | Level Four |
|---|---|---|---|---|
| Norovirus | 10 strains[a] | 20 strains[b] | 30 strains[b] | 40 strains[b] |
| Hepatitis A | 10 strains[c] | 20 strains[d] | 30 strains[d] | 40 strains[d] |
| Enterovirus | 10 strains[e] | 20 strains[f] | 30 strains[f] | 40 strains[f] |

### Norovirus Panels

**Level One** *([a]must include):*

**Panel A**

| | |
|---|---|
| HM175/18f (subgenotype 1B) | ATCC #VR-1402 (or equivalent) |
| Poliovirus 1 (attenuated) | ATCC #VR-1562 (or equivalent) |
| Feline calicivirus | ATCC #VR-2057 |
| Murine calicivirus | |

**Levels Two, Three and Four** *([b]must include):*

**Panel A** representatives ***plus:***

**Panel B**

| | |
|---|---|
| HAV; (subgenotype 1A) | ATCC #VR-2281 (or equivalent) |
| Coxsackievirus A3 | ATCC #VR-1007 (or equivalent) |
| Echovirus 1 | ATCC #VR-1038 (or equivalent) |
| Rotavirus; | ATCC #VR-2018 (or equivalent) |
| Astrovirus | |
| San Miguel Sea lion virus (if available) | |
| *Escherichia coli (1)* | |
| *Salmonella sp.(1)* | |
| *Shigella sp.(1)* | |
| *Vibrio sp. (1)* | |
| *Listeria sp. (1)* | |

## Hepatitis A Panels

**Level One** *(c must include):*

**Panel C**

| | |
|---|---|
| norovirus genogroup I | |
| norovirus genogroup II | |
| Poliovirus 1 (attenuated); | ATCC #VR-1562 (or equivalent) |
| Coxsackievirus A3 | ATCC #VR-1007 (or equivalent) |

**Levels Two, Three and Four** *(c must include)*:

**Panel C** representatives ***plus***

**Panel D**

| | |
|---|---|
| Echovirus 1 | ATCC #VR-1038 (or equivalent) |
| Rotavirus | ATCC #VR-2018 (or equivalent) |
| Feline calicivirus | ATCC #VR-2057 |
| Astrovirus | |
| *Escherichia coli (1)* | |
| *Salmonella sp.(1)* | |
| *Shigella sp.(1)* | |
| *Vibrio sp. (1)* | |
| *Listeria sp. (1)* | |

## Enterovirus Panels:

**Level One** *(c must include):*

**Panel E**

| | |
|---|---|
| norovirus genogroup I | |
| norovirus genogroup II | |
| HM175/18f (subgenotype 1B) | ATCC #VR-1402 (or equivalent) |

**Levels Two, Three and Four** *(c must include)*:

**Panel E** representatives ***plus***

**Panel F**

| | |
|---|---|
| HAV (subgenotype 1A) | ATCC #VR-2281 (or equivalent) |
| Rotavirus | ATCC #VR-2018 (or equivalent) |
| Feline calicivirus | ATCC #VR-2057 |
| *Escherichia coli (1)* | |
| *Salmonella sp.(1)* | |
| *Shigella sp.(1)* | |
| *Vibrio sp. (1)* | |
| *Listeria sp. (1)* | |

# VI. Protozoan Parasites

## A. *Cyclospora cayetanensis*

### a. Inclusive Panel

As many geographic and outbreak isolates as are available

### b. Exclusive Panel

***Cyclospora* spp.**

*C. cercopitheci*
*C. colobi*
*C. papionis*

***Eimeria* spp.**

*E. acervulina*
*E. bovis*
E. burnetti
*E. maxima*
*E. mitis*
*E. mivati*
*E. necatrix*
*E. nieschulzi*
*E. praecox*
*E. tenella*

***Additional Microorganisms***

*Cryptospordium spp*
*Apicomplexa*
*Bacterial isolates*

## B. *Cryptosporidium* spp.

**Inclusive Panel**

*C. hominis*
*C. parvum* (multiple strains available)

**Exclusive Panel**

*C. baileyi*
*C. canis*
*C. cuniculus*
*C. felis*
*C. meleagridi*
*C. muris*
*C. serpentis*
*Cyclospora ssp.*
*Apicomplexa*
*Bacterial isolates*

# Guidelines for the Validation of Chemical Methods for the FDA FVM Program

*2nd Edition*

US Food & Drug Administration
Office of Foods and Veterinary Medicine

April 2015

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***Center for Food Safety and Applied Nutrition***
Office of Regulatory Science
Office of Food Safety
Office of Applied Research and Safety Assessment

***Center for Veterinary Medicine***
Office of Research
Office of New Animal Drug Evaluation

***Office of Regulatory Affairs***
Office of Regulatory Science
ORA Laboratories

## APPROVAL PAGE

This document is approved by the FDA Foods and Veterinary Medicine (FVM) Science and Research Steering Committee (SRSC). The FVM SRSC Project Manager is responsible for updating the document as change requirements are met, and disseminating updates to the SRSC and other stakeholders, as required.

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ORA, Member of the ORA Scientific Advisory Council

US Food & Drug Administration
Office of Foods and Veterinary Medicine

# Guidelines for the Validation of Chemical Methods for the FDA FVM Program, *2nd Edition*

## TABLE OF CONTENTS

# 1.0 INTRODUCTION

## 1.1 Purpose

The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety of approximately 80% of the nation's food supply. FDA laboratories contribute to this mission through routine surveillance programs, targeted regulatory analyses, and emergency response when contaminated food or feed is detected or suspected in a public health incident. The effectiveness of these activities is highly dependent on the quality and performance of the laboratory methods needed to support regulatory compliance, investigations and enforcement actions. To ensure that the chemical methods employed for the analysis of foods and feeds meet the highest analytical performance standards appropriate for their intended purposes, the FDA Office of Foods and Veterinary Medicine (OFVM) through the Science and Research Steering Committee (SRSC) has established criteria by which all Foods and Veterinary Medicine (FVM) Program chemical methods shall be evaluated and validated. This document defines four standard levels of performance for use in the validation of analytical regulatory methods for chemical analytes in foods and feeds.

## 1.2 Scope

These criteria apply to FDA laboratories as they develop and participate in the validation of analytical regulatory methods for chemical analytes in anticipation of Agency-wide FVM Program implementation. These criteria do not apply to methods developed by or submitted to FDA under a codified process or official guidance (e.g., in the Code of Federal Regulations, CPGs, etc.) such as for veterinary drug approval. For such studies, the appropriate Center for Veterinary Medicine (CVM) or other Program guidance documents should be followed. This guidance is a forward-looking document; the requirements described here will only apply to *newly*-developed methods and significant modifications to existing methods (see Requirements). Once a method has been validated at the appropriate level, it can be implemented according to OFVM document, FDA-OFVM-3, "Methods Development, Validation, and Implementation Program", which establishes a standard operating procedure for the methods development, validation and implementation process [1]. For example, for a multi-laboratory validated method to be used in a widespread regulatory application, it can be implemented by other FDA laboratories following the method verification process. However, method verification is normally part of a local laboratory's quality control procedures and is not considered within the scope of this validation document.

## 1.3 Administrative Authority and Responsibilities

All criteria established in this document for analytical method validation have been adopted and approved by the OFVM and the SRSC. The OFVM document, FDA-OFVM-3, establishes the standard operating procedure for the approval and tracking of method development and validation activities within the FVM Program [1]. Single laboratory validation (SLV) studies (including both Level 1 and Level 2 validations) can be managed wholly by the respective Center and Office line management structure. Oversight and coordination of multi-laboratory validation (MLV) studies (including both Level 3 and Level 4 validations) are the responsibility of the Methods Validation Subcommittees (MVS).

## 1.4 The Method Validation Subcommittee

Under the charge of the SRSC, the Chemistry Methods Validation Subcommittee (CMVS) will have oversight responsibility for MLV studies involving chemical methods associated

with the FVM Program which are intended for use in a regulatory context. The CMVS is a subcommittee of the Chemistry Research Coordinating Group (CRCG), which reports directly to the SRSC. The CMVS is governed by the organizational structure, roles and responsibilities as detailed in its charter [2]. Briefly, the CMVS will oversee and coordinate, in collaboration with the originating laboratory, all MLV studies for chemical methods developed within the FDA OFVM Enterprise to support regulatory analytical needs. This includes the evaluation and prioritization of proposed MLV studies as well as evaluation of completed MLV studies and reports. Submissions of chemical validation proposals, reports, questions, *etc.* can be directed to the CMVS through a central email account:

*Chemistry.mvs@fda.hhs.gov*

However, where possible, MLVs should be discussed in appropriate Technical Advisory Groups or with the CRCG to ensure the broadest possible consideration of factors before committing resources to an MLV.

### 1.5 General Responsibility of the Originating Laboratory

It is the responsibility of the originating laboratory to ensure proper adherence to all criteria described in this document. The originating laboratory should work in consultation with the CMVS and/or its designated Technical Advisory Group (TAG) throughout the multi-laboratory validation process. It will be the responsibility of the originating laboratory to include their respective QA/QC manager in all aspects of the validation process.

### 1.6 Overview of Method Validation

Method validation is the process of demonstrating or confirming that a method is suitable for its intended purpose. The purpose of these methods may include but is not limited to qualitative analysis, quantitative analysis, screening analysis, confirmatory analysis, limit tests, matrix extensions, platform extensions, and emergency/contingency operations. Validation includes demonstrating performance characteristics such as accuracy, precision, sensitivity, selectivity, limit of detection, limit of quantitation, linearity, range, and ruggedness, to ensure that results are meaningful and appropriate to make a decision. Method validation is a distinct phase from method development/ optimization and should be performed *subsequent* to method development. Methods may be validated for one or more analytes, one or more matrices, and one or more instruments or platforms. The method is validated by conducting experiments to determine the specific performance characteristics that serve to define and quantify method performance.

### 1.7 Applicability

This document establishes validation criteria for regulatory methods that are to be widely used to detect chemical analytes in food, feed and other FDA regulated products covered by the FVM Program including, but not limited to, the following:

Chemotherapeutic Residues
Color Additives
Decomposition Products
Dietary Supplement Ingredients/Adulterants
Elemental and Metals
Food and Feed Additives and Preservatives
Food Allergens
Gluten

Intentional Adulterants/Poisons
Mycotoxins
Nutrients
Persistent Organic Pollutants
Pesticides
Seafood and plant toxins
Toxic Elements
Veterinary Drug Residues

Please note that although these guidelines mainly cover multi-laboratory validations, criteria for several validation levels are discussed and are differentiated from full MLVs. There are situations where a method is being extended to handle what is likely to be a very limited (perhaps one time) use by one laboratory and is therefore not intended for Agency-wide regulatory use, thus would be validated at a lower level. For example, when a single pesticide laboratory receives several new food matrices for multi-residue analyses that were not covered in the previous validation of the method, these guidelines would not generally be required and a more abbreviated validation/verification within the pesticide program's guidelines may be acceptable.

### 1.8 Requirements

Method validation is required for:

- Submission of a new or original method.
- Expansion of the scope of an existing method to include additional analytes.
- Expansion of the scope of an existing method to include additional matrices.
- Changes in the intended use of an existing method (*e.g.*, screening vs. confirmatory).
- Modifications to a method that may alter its performance specifications (*e.g.*, modifications that could significantly affect the precision and accuracy, changes to the fundamental science of an existing method, significant changes to reagents, apparatus, instrumental parameters, sample preparation and/or extraction, or modification of a method's range beyond validated levels). Some examples of allowable modifications that would not require further validation are provided in the document, ORA-LAB.5.4.5 Attachment A-Modification Criteria [3].

# 2.0 CRITERIA AND GUIDANCE FOR THE VALIDATION OF CHEMICAL METHODS

## 2.1 General Validation Tools and Protocol Guidance

There are a number of excellent references and guides available providing further information on method validation for chemical methods [3-20]. The following provides some general guidelines/tools that should be used to assess method performance:

General Protocol: Prepare and analyze method blanks, matrix blanks, reference materials (if available) and matrix spikes (using matrix blanks if available) of known concentration as generally described under the Methods Validation Levels section and Table 1 below. Accuracy or bias and precision are calculated from these results. Data will also be used to evaluate matrix effects and ruggedness/robustness of the method resulting from changes in the sample matrix.

The following general validation tools should be used to generate method performance characteristics as described in the Performance Characteristics section below.

*Blanks*: Use of various types of blanks enables assessment of how much of the result is attributable to the analyte in relation to other sources. Blanks are useful in the determination of limit of detection.

*Reference materials and certified reference materials*: The use of known reference materials (when available and applicable) should be incorporated to assess the accuracy or bias of the method, as well as for obtaining information on interferences.

*Matrix Blank*: This type of blank is a substance that closely matches the samples being analyzed with regard to matrix components. Matrix blanks are used to establish background level (presence or absence) of analyte(s) and to verify that sample matrix and equipment used does not interfere with or affect the analytical signal.

*Matrix Spikes (Laboratory Fortified Matrix)*: Recovery determinations can be estimated from fortification or spiking with a known amount of analyte and calculation of spike recoveries. (Note: spike recovery may not be accurately representative of recovery from naturally incurred analytes.) Matrix effects can also be assessed with these samples. Accuracy or bias and precision are calculated from these results. The data can also be used to evaluate robustness of the method resulting from changes in the sample matrix.

*Incurred Samples*: This type of sample contains (not laboratory fortified) the analyte(s) of interest (if available) and can be used to evaluate precision and bias (if analyte concentration(s) are reliably known). Analyte recovery can also be evaluated through successive extractions of the sample and/or comparison to another analytical procedure with known bias.

*Reagent Blank*: This type of blank incorporates all reagents used in the method and is subjected to all sample processing operations. It serves to verify that reagents are analyte free and the equipment used does not interfere with or affect the analytical signal.

*Replicate Analyses*: The precision of the analytical process can be evaluated using replicate analyses. The originating laboratory should assure that adequate sample replicates are

performed and that results from replicate measurements of each analyte are compared. Minimally, the method repeatability should be evaluated.

*Interferences*: Spectral, physical, and chemical interferences can be evaluated by analyzing samples containing various suspected interferences. Carryover should be evaluated using the incorporation of blanks immediately following standards and samples.

*Statistics*: Statistical techniques are employed to evaluate accuracy, trueness (or bias) precision, linear range, limits of detection and quantitation, and measurement uncertainty.

### 2.2 Reference Method

A reference method is a method by which the performance of an alternate or new method may be measured or evaluated. For chemical analytes, an appropriate reference method is not always identifiable or available. However, there are some instances in which the use of a reference method is appropriate such as when replacing a method specified for use in a compliance program. Consultation between the originating laboratory and the CMVS and the Program Office is suggested when deciding if the use of a reference method will be necessary.

### 2.3 Performance Characteristics

Performance characteristics that should be evaluated in order to validate a method will vary depending on the intended use of the method, the type of method (*e.g.*, quantitative vs. qualitative), and the degree to which it has been previously validated (e.g., matrix extension, analyte extension, platform extension). Although definitions of these characteristics are included in Appendix 1, this document is not meant to address the various ways of calculating characteristics such as method detection level, limit of detection or limit of quantitation.

*Performance Characteristics for Validation of New Quantitative Methods*: Validation of new quantitative methods should include at a minimum evaluation of the following performance characteristics: accuracy, precision, selectivity, limit of detection, limit of quantitation, linearity (or other calibration model), range, measurement uncertainty, ruggedness, confirmation of identity and spike recovery.

*Performance Characteristics for Validation of New Qualitative Methods*: Validation of new qualitative methods should include at a minimum evaluation of the following performance characteristics: sensitivity, selectivity, false positive rate, false negative rate, minimum detectable concentration, ruggedness, and confirmation of identity.

*Performance Characteristics for Validation of Method Extensions*: Validating the extension of methods that have previously been validated requires a careful evaluation of the intended purpose of the extension. In cases where the sample preparation and/or the extraction procedure/analytical method is modified from the existing test procedure, it should be demonstrated that the modifications do not adversely affect the precision and accuracy of the data obtained. In order to implement the modified method, generally the standard or existing method is first performed. The modified method performance then is verified by comparison with that of the original method.

## 2.4 Confirmation of Identity

Confirmation of identity for each analyte must be performed as part of the method validation for regulatory enforcement for both qualitative and quantitative methods. Unambiguous confirmation of identity usually requires analytically identifying key features of each analyte in the scope of the new method being validated such as with mass spectral fragmentation patterns or by demonstration of results in agreement with those obtained using an independent analysis.

FDA has issued guidance documents on the development, evaluation, and application of mass spectrometric methods for confirming the identity of target analytes including: CVM Guidance for Industry 118: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues [4] and ORA-LAB.010, Guidance for the Analysis and Documentation to Support Regulatory Action on Pesticide Residues [5]. Following the CVM guidance is required for veterinary drug residue methods. The ORA-LAB.010 document was written specifically for pesticide analyses. For other types of chemical contaminants in food (e.g. food additives, mycotoxins, etc.), the CVM document should be followed because it was written as a Guidance for Industry and therefore has been more widely internally and externally reviewed and distributed. In addition, OFVM is currently drafting a supplement to CVM Guidance for Industry 118 specifically addressing the use of high resolution mass spectrometry and the evaluation of exact mass measurement data.

## 2.5 Method Validation Levels

The following describes the four standard levels of performance defined for method validation of analytical regulatory methods for chemical analytes in foods. This approach is based on the Food Emergency Response Network (FERN), SOP No: FERN-ADM.0008.00, FERN Validation Guidelines for FERN Chemical, Microbiological, and Radiological Methods [6], as well as AOAC guidelines for single-laboratory validation [7] and collaborative studies [8]. Key validation parameters for each level are summarized in Table 1. It is the responsibility of the originating (developing) laboratory to determine the appropriate level of validation required up to and through single laboratory validations. It is highly recommended that originating laboratories work with the appropriate Technical Advisory Group when determining the appropriate level of validation.

NOTE: *Not all methods will or should be validated to the highest level.*

### Level One

This is a single laboratory validation level with the lowest level of validation requirements and is appropriate for emergency/limited use. Performance of the method at this initial level of scrutiny will determine, in part, whether further validation is useful or warranted.

***Intended Use:*** emergency/limited use/matrix extension/analyte extension/ platform extension. Examples of where Level One validation would be acceptable include, isolated consumer complaints, single-occurrence samples, and application of a method developed for a specific analyte(s) to a matrix, not previously validated in response to a real or perceived threat to food safety or public health. Validation of method performance with a new matrix is intended to assure that the new matrix will produce accurate and reliable results for all the analytes in the scope of the method. Generally, all targeted analytes still must be included in matrix spikes at this level, if widespread use in this matrix is anticipated for regulatory purposes. As the first level of validation of methods for matrix, analyte or platform extension/emergency use, it would be expected that a

more rigorous single laboratory validation at least equivalent to Level Two below would be performed before more widespread non-emergency regulatory use.

**Level Two**

This is a single laboratory validation level. The originating lab has conducted a comprehensive validation study, with performance criteria similar to an AOAC Single Laboratory Validation study. If appropriate, a comparison with an existing reference method has been performed. Some of the criteria of the study may be at a lower level than the AOAC Single Laboratory Validation study, but are appropriate for the developing method at this stage.

***Intended Use:*** Routine regulatory testing, emergency needs, minor method modifications, analyte and matrix extensions of screening methods. If a method validated at this level is expected to have use that is widespread, long term, of high public visibility or potentially involved in international trade conflicts, its validation should be extended to at least Level Three below.

**Level Three**

This is a multi-laboratory validation level. Level Three validation employs a minimum of one collaborating laboratory in addition to the originating laboratory. Most of the criteria followed by the originating lab are at a level similar to the AOAC full collaborative study level with comparison to an existing reference method when available and appropriate. The additional collaborating laboratories follow many of the criteria found in an AOAC collaborative study. The main differences are that Level Three validation employs at least one additional collaborating laboratory instead of the eight to ten used by AOAC and requires fewer replicates for each food matrix/spike level.

**Intended Use**: Methods validated to this level of scrutiny are acceptable for use in all regulatory circumstances including screening analyses, confirmatory analyses, regulatory surveys, and compliance support. If the method is expected to have use that is widespread, long term, of high public visibility or involved in international trade conflicts, it may be appropriate to have its validation extended to Level Four.

**Level Four**

This validation level has criteria equivalent to a full AOAC or ISO Collaborative Study. Any method reaching this level of validation should be able to be submitted for adoption by the AOAC as a fully collaborated method.

**2.6 Acceptability Criteria**

There are various acceptability ranges for method validation performance criteria that may be appropriate depending on the application or intended use of the methodology and especially the levels of concern, action levels or tolerance for the chemical analyte. Some examples of acceptability ranges used by various national and international organizations and their sources are provided in Appendix 2. Acceptable spike recoveries vary with analyte concentration as indicated in Appendix 2 (e.g., recoveries may fall in approximately the 80-120% range for quantitative methods at the 1 µg/g (ppm) concentration). Repeatability and reproducibility also vary with analyte concentration. The acceptability ranges in Appendix 2 provide approximate target ranges for method developers and the MVS and are not rigid binding guidelines. It is recognized that for some situations such as with difficult matrices, extremely low analyte concentrations (e.g., chlorinated dioxins, persistent organic

pollutants), multi-residue methods and with emergency situations these general acceptability ranges may not be achievable or required.

**Table 1. Key Validation Parameter Requirements for Chemical Methods**

| | Level One: Emergency/ Limited Use | Level Two: Single Laboratory Validation | Level Three: Multi-Laboratory Validation | Level Four: Full Collaborative Study |
|---|---|---|---|---|
| Number participating labs | 1 | 1 | ≥ 2 | 8 (quantitative)<br>10 (qualitative) |
| Number of matrix sources per matrix* | ≥1 | ≥3 recommended where available | ≥3 recommended where available | ≥3 recommended where available |
| Number of analyte(s) spike levels for at least one matrix source** | ≥2 spike levels + 1 matrix blank | ≥3 spike levels + 1 matrix blank | ≥3 spike levels + 1 matrix blank | ≥3 spike levels + 1 matrix blank |
| Replicates required per matrix source at each level tested per laboratory | ≥2 (quantitative)<br>≥2 (qualitative) | ≥2 (quantitative)<br>≥3 (qualitative) | ≥2 (quantitative)<br>≥3 (qualitative) | ≥2 (quantitative)<br>≥3 (qualitative) |
| Replicates required at each level tested per laboratory if only one matrix source used | ≥4 (quantitative)<br>≥6 (qualitative) | ≥6 (quantitative)<br>≥9 (qualitative) | ≥3 (quantitative)<br>≥6 (qualitative) | ≥2 (quantitative)<br>≥6 (qualitative) |

*If a variety of food matrices with differing physical and chemical properties are selected, the number of sources for each food sample matrix may be one or more, but if only one food matrix is studied then ≥3 sources are recommended where available. The number of matrix sources may be reduced, particularly if it is difficult to obtain blank matrix sources, as long as the total number of spike levels and matrix combinations are adequate (e.g., 6 replicates or greater at each spike level for quantitative methods and 9 replicates or greater for qualitative methods).

** Number of spike levels is recommended for at least one source of matrix. Other similar sources of matrix (*e.g.*, within the same category; see Appendix 4) may be studied at one or two spike levels (*e.g.*, at an action/guidance or tolerance level or close to the lower limit of quantitation/detection).

## 3.0 ADDITIONAL PROCEDURAL GUIDANCE

In addition to the criteria described above in Table 1 for standard quantitative and qualitative methods, additional guidance is provided in this section for specific types of methods or validation situations.

### 3.1 Platform/Instrumentation Extension

Expanding the use of a validated method to include another significantly different instrument or platform requires further validation. Such instances include the use of an instrument or platform similar in scope and function to that currently validated and approved for use; however, it may have major differences in configuration, or detection scheme.

Platform extension validation should generally be performed using Table 1, Level 2 as a guide and should compare the proposed new platform to the platform used in the reference method. In planning platform extension validation, one must determine what degree of cross-correlation between the results obtained on the two platforms will be acceptable.

Examples:
Method A is a validated method for the screening of pesticides on a gas chromatograph coupled to a single quadrupole mass spectrometer (GC-MSD). Gas chromatography coupled to a triple quadrupole mass spectrometer (GC-QQQ), offers certain advantages over the GC-MSD platform in terms of sensitivity, selectivity and scope. In this instance, a comparative method extension validation is indicated to ensure equivalent results. However, if new analytes are added to the scope of the method via the use of the new platform, a new method validation is indicated for the GC-QQQ method.

Method Z is a validated method for the screening of polycyclic aromatic hydrocarbons in seafood using liquid chromatography with a fluorescence detector (LC-FLD). A laboratory would like to transfer this method to a liquid chromatography system that utilizes only a diode-array detector (LC-DAD). In this instance, a comparative method extension validation would be indicated to ensure that the new detection system produces equivalent results to the originally validated method.

### 3.2 Analyte Extension

Multi-residue, multi-class methods are becoming more common. Many of these methods are semi-quantitative (limits tests) or qualitative broad band screens. Performance requirements for these types of procedures are described below. However, if a multi-residue method is meant to be used for quantitation, the same performance characteristics as required for single analyte methods should be evaluated for each analyte (accuracy, precision, selectivity, limit of detection, limit of quantitation, linearity range, uncertainty, and ruggedness). It is understood that with a large multi-residue method , not all analytes will meet the recommended acceptability ranges listed in Appendix 2, but the performance for each compound should be tested and reported so that the accuracy and precision are known for any given analyte and are sufficient for the intended purpose of the method.

When new analytes are added to a quantitative multi-residue method, tests should be performed to ensure that the addition of new compounds do not affect the performance of the instrumental conditions, e.g. duty cycle or scan rates for other eluting analytes, and that

the analytes do not present a chemical or physical interaction with the stabilities of the other tested analytes.

### 3.3 Food Matrix Extension

The validation of method performance with a new matrix is intended to assure that the method will continue to produce accurate and reliable results. Emergency matrix extensions (Level 1 in Table1) are intended for those instances in which a validated method is used with a matrix not previously validated in response to a real or perceived threat to food safety or public health, and in this type of urgent situation it is not expected that the MVS would be consulted. Matrix extensions of validated methods that are intended to increase the regulatory scope and applicability on a recurring basis would minimally fall under Level 2 validation in Table 1. This section provides guidance to extend validated methods to matrices in anticipation that these food commodities will be included in Agency-wide testing. Method developers may wish to consult with the appropriate Technical Advisory Group or MVS before initiating any Level 2 validation work on matrix extension.

It is generally assumed that the more closely related a new food matrix is to a previously validated matrix for a defined analyte, the greater the probability that the new matrix will behave similarly. It is also usually the case that the regulatory chemical methods employed by FDA are used to analyze a diversity of products representing a large spectrum of matrices. It becomes unfeasible to carry out a matrix extension validation for each single matrix in order to expand the scope of the method. A more reasonable approach to demonstrate the applicability of a method to a set of product matrices is to validate the method for different "categories" of products. For instance, a multi-residue pesticide method can be validated for "high-sugar", "high-fat", "high-water", "dry" and "high-protein" matrices. Appendix 4 provides guidance on commodity categories and gives examples of representative matrices in each category.

The number of different food categories to be validated depends on the applicability and intended use of the method. If the method is specific to only one category, only one type of food need be included. If the applicability is wider (e.g., detection of phthalates in processed foods), then an appropriate number of food categories should be included to represent all anticipated matrices. Depending on how many categories will be validated, a minimum of 1 – 3 representative matrices from each category should be selected.

### 3.4 Limit Tests (common semi-quantitative screening method)

One specific category of qualitative methods includes limit tests (binary or pass/fail tests) for analytes that have a defined level of concern. The purpose of these screening methods is to determine if analyte is present with a concentration near or above the level of concern. This is in contrast to screening methods whose intended purpose is to determine the presence or absence of an analyte at any level. Limit test method validations must include determination of the precision of the method for an analyte(s) at the level(s) of concern.

Limit test screening methods, in general, should avoid false negatives with false negative rates representing less than 5% of the analytical results. The occurrence of false positives is less critical since presumptive positives are further analyzed by quantitative or confirmatory methods. However, false positive rates should typically be less than 10-15% to avoid unnecessary confirmatory testing. Ideally, limit tests are capable of rapidly screening a large number of samples to minimize the need for additional analysis. A common approach used in limit test screening methods is to use a confidence interval to set a laboratory threshold or cut-off value whereby only responses above that value require further testing. For a limit

test based on an instrument response, a threshold or cut-off value can be determined by a confidence limit, based on an estimate of the standard deviation of the response or concentration of an analyte in samples fortified with the analyte at the level of concern.

Example:
Milk samples (n=21) were fortified with sulfamethazine at the level of concern (10 ng/mL). A LC-MS/MS limit test screening method was used to measure this drug in the extracted milk samples. The mean concentration found was to be 10.99 ng/mL with a standard deviation of 2.19. A threshold or cut-off value was calculated so that 95% of samples containing sulfamethazine at or above 10 ng/mL would have a response above the threshold value:

Threshold value = [mean concentration – (t * standard deviation)]
= [10.99 – (1.725 * 2.19)] = 7.21 ng/mL

*Where t = one-tailed Student's t value for n-1 degrees of freedom at the 95% confidence level*

This approach can also be used for immunosorbent assays such as enzyme linked immunosorbent assay (ELISA) or optical biosensor assays. These tests may be non-competitive (direct measurement of analyte response) or competitive (indirect measurement). Analysis of data from a competitive immunosorbent test should account for the fact that the observed response decreases with increasing analyte concentration; therefore, a response lower than the threshold or cut-off would be considered a presumptive positive response. For immunosorbent assays, it is also important to measure the response observed for blank matrix samples and to verify that the blank response is distinguishably (statistically) different from that of the threshold.

*Performance characteristics of limit tests:*
Validation of new limit tests should include, at a minimum, evaluation of the following performance characteristics: sensitivity, specificity, precision, threshold or cut-off value, false positive rate, false negative rate, minimum detectable concentration (should be lower than the threshold/cut-off value), and ruggedness/robustness.

### 3.5 Qualitative Broad-band Analyte Screening

Broad-band methods that can detect many compounds are being utilized more frequently as an initial screening step as part of chemical contaminant testing in FDA laboratories. These methods usually involve mass spectrometric analyses and provide qualitative information. For example, the data obtained may be compared to an established reference such as a database of compounds with exact mass and molecular formula information or spectra in a compiled library. For regulatory action, any positive findings from this screen should be confirmed by a targeted method (for example using a LC-MS/MS or GC-MS/MS platform).

Typically, initial validation of these methods is performed using a limited set of representative analytes and representative matrices. For example, sets of analytes that contain compounds from a variety of chemical classes from the area of interest (e.g. pesticides, veterinary drug residues, or common chemical toxins) are tested with the method using representative matrices. The performance characteristics that may be evaluated include: sensitivity, selectivity, false positive rate, false negative rate, minimum detectable concentration, ruggedness, and confirmation of identity. It is understood that the method

performance may vary with the different classes of compounds, but it is important to have an initial evaluation of the method's capabilities.

Laboratories continuously expand the scope of these broad-band methods by adding new analytes that come to their attention through various sources of intelligence. In addition, a new compound might be found in a sample after acquired data are compared to the reference databases. In these cases, some verification that the analyte can be detected reliably by the screening method is required. When a new compound is added to the scope of a qualitative method, it should first be determined whether this compound belongs to a class of compounds that has already been validated for the broad-band method. If the new compound shares chemical characteristics with an existing class of compounds in the scope of the method, then it may suffice to select a few representative matrices, perform a single level spike in these representative matrices in duplicate and determine that reproducible recovery is obtained in order to assess whether the analyte can be detected effectively by the method. Scenarios that may require a full validation would include a new analyte being added to the scope of the broad-band method that was not represented by any of the compound classes already in the scope. Also, if the new analyte requires modifications in the extraction protocol due to its chemical characteristics, then its inclusion in the scope should be fully validated as recommended by this guidance.

Although positive findings by the broad-band method are subjected to confirmatory testing using a targeted method, it is still important to determine, through proper validation and verification protocols, that the broad-band method does not give rise to a high number of false negative findings. False negative in this context means the method fails to detect a residue in its scope when the residue is present in the matrix at or above the level of concern or minimum detectable concentration. While the positive finding by the broad-band method is subjected to further analysis and scrutiny, negative findings are upheld as such and a regulatory decision is made based on these results, *e.g.*, to release the products into commerce.

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## APPENDIX 1 - Glossary of Terms

Generally, references 13-17 were utilized in preparation of this glossary.

**Accuracy:** The closeness of agreement between a test result and an accepted reference value. When applied to test results, accuracy includes a combination of random and systematic error. When applied to test method, accuracy refers to a combination of trueness and precision.

**Action level:** Level of concern or target level for an analyte that must be reliably identified or quantified in a sample.

**Analyte:** The chemical substance measured and/or identified in a test sample by the method of analysis.

**Analytical batch:** An analytical batch consists of samples, standards, and blanks which are analyzed together with the same method sequence and same lots of reagents and with the manipulations common to each sample within the same time period (usually within one day) or in continuous sequential time periods.

**Bias:** The difference between the expectation of the test result and the true value or accepted reference value. Bias is the total systematic error, and there may be one or more systematic error components contributing to the bias.

**Blank:** A substance that does not contain the analytes of interest and is subjected to the usual measurement process. Blanks can be further classified as method blanks, matrix blanks, reagent blanks, instrument blanks, and field blanks.

**Calibration:** Determination of the relationship between the observed analyte signal generated by the measuring/detection system and the quantity of analyte present in the sample measured. Typically, this is accomplished through the use of calibration standards containing known amounts of analyte.

**Calibration Standard:** A known amount or concentration of analyte used to calibrate the measuring/detection system. May be matrix matched for specific sample matrices.

**Carryover:** Residual analyte from a previous sample or standard which is retained in the analytical system and measured in subsequent samples. Also called *memory*.

**Certified Reference Material (CRM):** Reference material accompanied by documentation (certificate) issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceability, using valid procedures. Note: Standard Reference Material (SRM) is the trademark name of CRMs produced and distributed by the National Institute of Standards and Technology (NIST).

**Check Analysis:** Result from a second independent analysis which is compared with the result from the initial analysis. Typically, check analyses are performed by a different analyst using the same method.

**Confirmation of Identity:** Unambiguous identification of an analyte(s) by a highly specific technique such as mass spectrometry or by demonstration of results from two or more independent analyses in agreement.

**Confirmatory Analysis/Method:** Independent analysis/method used to confirm the result from an initial or screening analysis. A different method is often used in confirmation of screening results.

**Cut-off Concentration:** In qualitative analysis, the concentration of the analyte that is either statistically lower than the level of concern (for limit tests) or at which positive identification ceases (for confirmation of identity methods). See also *Threshold Value.*

**False Negative Rate:** In qualitative analysis, a measure of how often a test result indicates that an analyte is not present, when, in fact, it is present or, is present in an amount greater than a threshold or designated cut-off concentration.

**False Positive Rate:** In qualitative analysis, a measure of how often a test result indicates that an analyte is present, when, in fact, it is not present or, is present in an amount less than a threshold or designated cut-off concentration.

**Fitness for Purpose:** Degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose.

**Guidance Level:** Level of concern or action level issued under good guidance practices that must be reliably identified or quantified in a sample.

**Incurred Samples:** Samples that contain the analyte(s) of interest, which were not derived from laboratory fortification but from sources such as exogenous exposure or endogenous origin. Exogenous exposure includes, for example, pesticide use, consumption by an animal, or environmental exposure.

**Interference:** A positive or negative response or effect on response produced by a substance other than the analyte. Includes spectral, physical, and chemical interferences which result in a less certain or accurate measurement of the analyte.

**Intermediate Precision:** Within-laboratory precision obtained under variable conditions, e.g., different days, different analysts, and/or different instrumentation.

**Internal Standard:** A chemical added to the sample, in known quantity, at a specified stage in the analysis to facilitate quantitation of the analyte. Internal standards are used to correct for matrix effects, incomplete spike recoveries, etc. Analyte concentration is deduced from its response relative to that produced by the internal standard. The internal standard should have similar physico-chemical properties to those of the analyte.

**Laboratory Fortified Matrix:** See *Matrix Spike.*

**Level of Concern:** Level of concern is the concentration of an analyte in a sample that has to be exceeded before the sample can be considered violative. This concentration can be a regulatory tolerance, safe level, action level, guidance level or a laboratory performance level.

**Limit of Detection (LOD):** The minimum amount or concentration of analyte that can be reliably distinguished from zero. The term is usually restricted to the response of the detection system and is often referred to as the *Detection Limit.* When applied to the complete analytical method it is often referred to as the *Method Detection Limit* (MDL).

**Limit of Quantitation (LOQ):** The minimum amount or concentration of analyte in the test sample that can be quantified with acceptable precision. Limit of quantitation (or quantification) is variously defined but must be a value greater than the MDL and should apply to the complete analytical method.

**Limit Test:** A type of semi-quantitative screening method in which analyte(s) has a defined level of concern. Also referred to as binary or pass/fail tests.

**Linearity:** The ability of a method, within a certain range, to provide an instrumental response or test results proportional to the quantity of analyte to be determined in the test sample.

**Matrix:** All the constituents of the test sample with the exception of the analyte.

**Matrix Blank:** A substance that closely matches the samples being analyzed with regard to matrix components. Ideally, the matrix blank does not contain the analyte(s) of interest but is subjected to all sample processing operations including all reagents used to analyze the test samples. The matrix blank is used to determine the absence of significant interference due to matrix, reagents and equipment used in the analysis.

**Matrix Effect:** An influence of one or more components from the sample matrix on the measurement of the analyte concentration or mass. Matrix effects may be observed as increased or decreased detector responses, compared with those produced by simple solvent solutions of the analyte.

**Matrix Source:** The origin of a test matrix used in method validation. A sample matrix may have variability due to its source. Different food matrix sources can be defined as different commercial brands, matrices from different suppliers, or in some cases different matrices altogether. For example, if a variety of food matrices with differing physical and chemical properties are selected, the number of sources for each food sample matrix may be one or more.

**Matrix spike:** An aliquot of a sample prepared by adding a known amount of analyte(s) to a specified amount of matrix. A matrix spike is subjected to the entire analytical procedure to establish if the method is appropriate for the analysis of a specific analyte(s) in a particular matrix. Also referred to as a *Laboratory Fortified Matrix.*

**Method blank:** A substance that does not contain the analyte(s) of interest but is subjected to all sample processing operations including all reagents used to analyze the test samples. An aliquot of reagent water is often used as a method blank in the absence of a suitable analyte-free matrix blank.

**Method Detection Limit (MDL):** The minimum amount or concentration of analyte in the test sample that can be reliably distinguished from zero. MDL is dependent on sensitivity, instrumental noise, blank variability, sample matrix variability, and dilution factor.

**Method Development:** The process of design, optimization and preliminary assessment of the performance characteristics of a method.

**Method Validation:** The process of demonstrating or confirming that a method is suitable for its intended purpose. Validation includes demonstrating performance characteristics such as accuracy, precision, specificity, limit of detection, limit of quantitation, linearity, range, ruggedness and robustness.

**Method Verification:** The process of demonstrating that a laboratory is capable of replicating a validated method with an acceptable level of performance.

**Minimum Detectable Concentration (MDC):** In qualitative analysis, an estimate of the minimum concentration of analyte that must be present in a sample to ensure at a specified high probability (typically 95% or greater) that the measured response will exceed the detection threshold, leading one to correctly conclude that an analyte is present in the sample.

**Precision:** The closeness of agreement between independent test results obtained under specified conditions. The precision is described by statistical methods such as a standard deviation or confidence limit of test results. See also *Random Error*. Precision can be further classified as *Repeatability, Intermediate Precision*, and *Reproducibility*.

**Qualitative Analysis/Method:** Analysis/method in which substances are identified or classified on the basis of their chemical, biological or physical properties. The test result is either the presence or absence of the analyte(s) in question.

**Quantitative Analysis/Method:** Analysis/method in which the amount or concentration of an analyte may be determined (or estimated) and expressed as a numerical value in appropriate units with acceptable accuracy and precision.

**Random error:** Component of measurement error that in replicate measurements varies in an unpredictable manner. See also *Precision*.

**Range:** The interval of concentration over which the method provides suitable accuracy and precision.

**Reagent Blank:** Reagents used in the procedure taken through the entire method. Reagent Blanks are used to determine the absence of significant interference due to reagents or equipment used in the analysis.

**Recovery:** The proportion of analyte (incurred or added) remaining at the point of the final determination from the analytical portion of the sample measured. Usually recovery is expressed as a percentage.

**Reference material:** A material, sufficiently homogenous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process or in examination of nominal properties.

**Reference standard:** A standard, generally having the highest metrological quality available at a given location in a given organization, from which measurements are made or derived. Note: Generally, this refers to recognized national or international traceable

standards provided by a standards producing body such as the National Institute of Standards and Technology (NIST).

**Repeatability:** Precision obtained under observation conditions where independent test results are obtained with the same method on identical test items in the same test facility by the same operator using the same equipment within short intervals of time.

**Representative Analyte:** An analyte used to assess probable analytical performance with respect to other analytes having similar physical and/or chemical characteristics. Acceptable data for a representative analyte are assumed to show that performance is satisfactory for the represented analytes. Representative analytes should include those for which the worst performance is expected. Representative analytes are used mostly for non-targeted analysis and unknown screening procedures.

**Representative Matrix:** Matrix used to assess probable analytical performance with respect to other matrices, or for matrix-matched calibration, in the analysis of broadly similar commodities. For food matrices, similarity is usually based on the amount of water, fats, protein, and carbohydrates. Sample pH and salt content can also have a significant effect on some analytes.

**Reproducibility:** Precision obtained under observation conditions where independent test results are obtained with the same method on identical test items in different test facilities with different operators using different equipment.

**Ruggedness/Robustness:** A measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

**Screening Analysis/Method:** An analysis/method intended to detect the presence of analyte in a sample at or above some specified concentration (action or target level). Screening methods typically attempt to use simplified methodology for decreased analysis time and increased sample throughput.

**Selectivity:** The extent to which a method can determine particular analyte(s) in a mixture(s) or matrix(ces) without interferences from other components of similar behavior. Selectivity is generally preferred in analytical chemistry over the term *Specificity*.

**Sensitivity**: The change in instrument response which corresponds to a change in the measured quantity (*e.g.*, analyte concentration). Sensitivity is commonly defined as the gradient of the response curve or slope of the calibration curve at a level near the LOQ.

**Specificity**: In quantitative analysis, specificity is the ability of a method to measure analyte in the presence of components which may be expected to be present. The term *Selectivity* is generally preferred over Specificity.

**Spike Recovery:** The fraction of analyte remaining at the point of final determination after it is added to a specified amount of matrix and subjected to the entire analytical procedure. Spike Recovery is typically expressed as a percentage. Spike recovery should be calculated for the method as written. For example, if the method prescribes using deuterated internal standards or matrix-matched calibration standards, then the reported analyte recoveries should be calculated according to those procedures.

**Standard:** A substance of known identity and purity and/or concentration.

**Standard Reference Material (SRM):** A certified reference material issued by the National Institutes of Standards and Technology (NIST) in the United States. (www.nist.gov/SRM).

**Systematic error:** Component of measurement error that in replicate measurements remains constant or varies in a predictable manner. This may also be referred to as *Bias*.

**Threshold Value:** In qualitative analysis, the concentration of the analyte that is either statistically lower than the level of concern (for limit tests) or at which positive identification ceases (for confirmation of identity methods). See also *Cut-off Concentration*.

**Trueness:** The degree of agreement of the mean value from a series of measurements with the true value or accepted reference value. This is related to systematic error (bias).

**Uncertainty:** Non-negative parameter characterizing the dispersion of the values being attributed to the measured value.

## APPENDIX 2 – Examples of Acceptability Criteria for Certain Performance Characteristics

Examples of acceptability criteria are found in references 7,9,10,14 and 18. No single set of acceptability is going to be truly applicable to all methodology covered in the FVM program. However a good starting point for many methods is found in the Codex Alimentarius Commission, Procedural Manual, Twenty-second ed., 2014 [10]

### A. Quantitative Method Acceptability Criteria

**Table A2.1. Method Criteria for Method Levels at Increasing Orders of Magnitude** (reproduced in part from reference 10, Table 4, p. 72 and reference 7)

| ML* unit | 0.001 mg/kg | 0.01 mg/kg | 0.1 mg/kg | 1 mg/kg | 10 mg/kg | 100 mg/kg | 1 g/kg | 10 g/kg |
|---|---|---|---|---|---|---|---|---|
| Alternative ML* unit | 1 ppb | 10 ppb | 100 ppb | 1 ppm | 10 ppm | 100 ppm | 0.1% | 1 % |
| Concentration ratio of ML ($C_{ML}$) | $10^{-9}$ | $10^{-8}$ | $10^{-7}$ | $10^{-6}$ | $10^{-5}$ | $10^{-4}$ | $10^{-3}$ | $10^{-2}$ |
| Minimum applicable range | From 0.0006 to 0.0014 mg/kg | From 0.006 to 0.014 mg/kg | From 0.03 to 0.17 mg/kg | From 0.52 to 1.48 mg/kg | From 6.6 to 13.3 mg/kg | From 76 to 124 mg/kg | From 0.83 to 1.2 g/kg | From 8.8 to 11 g/kg |
| LOD (≤ mg/kg) | 0.0002 | 0.002 | 0.01 | 0.1 | 1 | 10 | 100 | 1000 |
| LOQ (≤ mg/kg) | 0.0004 | 0.004 | 0.02 | 0.2 | 2 | 20 | 200 | 2000 |
| $RSD_r$** | 22% | 22% | 11% | 8% | 6% | 4% | 3% | 2% |
| $PRSD_R$# | 22% | 22% | 22% | 16% | 11% | 8% | 6% | 4% |
| $RSD_R$## | ≤ 44% | ≤ 44% | ≤ 44% | ≤ 32% | ≤ 22% | ≤ 16% | ≤ 12% | ≤ 8% |
| Recovery | 40%-120% | 60%-115% | 80%-110% | 80%-110% | 80% - 110% | 90% - 107% | 95% – 105% | 97%-103% |

*ML is a method level and can be defined for the analyte(s)/sample matrice(s) combination as a maximum level, minimum level, normative level or concentration range depending on the intended use of the method.

"The $RSD_r$ or Repeatability Precision refers to the degree of agreement of results when conditions are maintained as constant as possible within a short period of time (e.g., relative standard deviation of replicates or best precision exhibited by a single laboratory). Typically, acceptable values for $RSD_r$ are between ½ and 2 times the value shown ($HorRat_r$ = $RSD_r$ (found, %)/ $RSD_r$ (calculated, %)). For concentration ratios ≥ 10-7 Horwitz theory is applied. For concentration ratios < $10^{-7}$, Thompson theory is applied.

#The $PRSD_R$ or Predicted Relative Reproducibility Standard Deviation is based on the Horwitz/Thompson equation. For concentration ratios < $10^{-7}$, Thompson theory is applied.

## The $RSD_R$ or Reproducibility Precision refers to the degree of agreement of results when operating conditions are as different as possible (*e.g.*, same test samples in different laboratories) and should be calculated from the Horwitz/Thompson equation. When the Horwitz/Thompson equation is not applicable (for an analytical purpose or according to a regulation) or when "converting" methods into criteria then it should be based on the $RSD_R$ from an appropriate method performance study. The ratio between the found and predicted value should be ≤ 2. ($HorRat_R$ = $RSD_R$ / $PRSD_R$ ≤ 2 )

## B. Qualitative Method Acceptability Criteria

There are significantly fewer examples of acceptability criteria for qualitative methods available. AOAC is using a relatively new Probability of Detection (POD) model as a way to characterize the performance of qualitative methods [9].

As discussed above, limit test screening methods, in general, should minimize false negatives particularly at the level of concern or reporting level. The occurrence of false positives is less critical since presumptive positives are further analyzed by quantitative or confirmatory methods. However, false positive rates should typically be less than 10-15% in order to avoid unnecessary confirmatory testing (14, 18).

### Table A2.2. General Method Criteria for Limit Tests/Screening Methods

| | |
|---|---|
| False Negative Rate | ≤ 5% at the level of concern[1] |
| False Positive Rate | ≤ 10-15% |

[1] Acceptable false negative rate depends significantly on the intended purpose of the method.

# APPENDIX 3 - Examples of Validation Plans

## A. Extension to other matrices with the same analyte(s) at Level One Validation

This scheme represents an emergency use method extension plan for Matrix Y and Analyte Z. This plan utilizes two different sources of matrix. *In cases where a representative matrix is being used to characterize a whole family of commodities, it is recommended that additional, different commodities from that family are used as "sources".* Note that this plan is for emergency use only – the new matrix (or matrices) cannot be officially included in the scope of the method until at the minimum a Level Two Validation is performed.

**Table A3.1. Plan for Matrix Extension (Level One Validation, Example)**

| | Matrix | Samples 1 & 2 | Analyte Z Fortified Samples 3 & 4 | Analyte Z Fortified Samples 5 & 6 | Analyte Z Fortified Samples 7 & 8 |
|---|---|---|---|---|---|
| Day 1 | Matrix Y (Source 1) | Blank | ½X Spike Level | X Spike Level | 2X Spike Level |
| Day 1 | Matrix Y (Source 2) | Blank | ½X Spike Level | X Spike Level | 2X Spike Level |

***Notes:***

*i. Test portion matrices listed as Matrix Y represent 2 different commercial brands.*
*ii. Fortification levels: fortification will be at the level of concern or action level (X) as stated in the method and at levels corresponding to 1/2X and 2X.*
*iii. Fortification of each matrix can be done on the same day.*
*iv. Other fortification plans meeting requirements specified in Table 1 may be used.*

## B. Extension to similar analytes in the same matrix at Level Two Validation

A validated method can be extended to other potential analyte(s) belonging to the same chemical group. For example, a toxin method can be extended to other toxins. An example of the composition of a set of validation studies for method extension is shown in the following table for new analytes Y and Z in canned corn from 3 different sources where the method is validated originally for analyte A in corn.

**Table A3.2. Plan for Extension to Similar Analytes (Level Two Validation, Example)**

| | Matrix | Analyte Y fortification levels | Analyte Z fortification levels |
|---|---|---|---|
| Day 1 | Corn 1,2,3 | 0, 1/2X, X, 2X | 0, 1/2X, X, 2X |
| Day 2 | Corn 1,2,3 | 0, 1/2X, X, 2X | 0, 1/2X, X, 2X |

| | | | |
|---|---|---|---|
| Day 3 | Corn 1,2,3 | 0, 1/2X, X, 2X | 0, 1/2X, X, 2X |

***Notes:***
*i. Three different commercial brands of same product will be analyzed.*
*ii. Fortification levels: fortification will be at the level of concern or action level (X) as stated in the method and at levels corresponding to 1/2X and 2X.*
*iii. Each analyte will be analyzed in blank matrix and at 1/2X, X and 2X fortification levels.*
*iv. Simultaneous analysis of the analytes can be undertaken if warranted.*
*v. Other fortification plans meeting requirements specified in Table 1 may be used.*

### C. Validation at Level Two for single matrix and single analyte

This plan utilizes 3 different commercial brands of one matrix. The single matrix is being validated for a single analyte.

**Table A3.3. Plan for Single Matrix and Single Analyte Level Two Validation (Example)**

| | Matrix 1<br>Source 1 | Matrix 1<br>Source 2 | Matrix 1<br>Source 3 |
|---|---|---|---|
| Day 1 | Blank<br>Fortified (X) | Fortified (X)<br>Fortified (2X) | Blank<br>Fortified (1/2X) |
| Day 2 | Fortified (2X)<br>Fortified (1/2X) | Blank<br>Fortified (1/2X) | Blank<br>Fortified (2X) |
| Day 3 | Fortified (1/2X)<br>Fortified (X) | Fortified (2X)<br>Blank | Fortified (X)<br>Fortified (X) |
| Day 4 | Fortified (2X)<br>Blank | Fortified (X)<br>Fortified (1/2X) | Fortified (2X)<br>Fortified (1/2X) |

***Notes:***
*i Sample matrix, represents one matrix from 3 different sources of matrix.*
*ii Fortification levels: fortification will be at the level of concern or action level (X) as stated in the method and at levels corresponding to 1/2X and 2X.*
*iii Each of 3 different sources of matrix will be analyzed 8 times (replicate analyses) over the course of experiment, two times unfortified, two times fortified at each level.*
*iv. The validation will take place over a period of 4 days.*
*v. Other fortification plans meeting requirements specified in Table 1 may be used.*

## APPENDIX 4 – Selection of Representative Matrices

Two tools that can aid in selection of representative matrices and CRMs when designing a validation protocol for a method intended to have applicability to a broad scope of products are shown below. Food composition varies greatly making the validation of methods intended for a wide variety of foods a difficult balance between available resources and sufficient validation with a variety of food types.

### A. Commodity groups and representative commodities

**Table A4.1. Vegetable and Fruits, Cereals and Food of Animal Origin** (reproduced in part from reference 14)

| Commodity groups | Typical commodity categories | Typical representative commodities |
|---|---|---|
| 1. High water content | Pome fruit | Apples, pears |
| | Stone fruit | Apricots, cherries, peaches |
| | Other fruit | Bananas |
| | Alliums | Onions, leeks |
| | Fruiting vegetables/cucurbits | Tomatoes, peppers, cucumber, melon |
| | Brassica vegetables | Cauliflower, Brussels sprouts, cabbage, broccoli |
| | Leafy vegetables and fresh herbs | Lettuce, spinach, basil |
| | Stem and stalk vegetables | Celery, asparagus |
| | Forage/fodder crops | Fresh alfalfa, fodder vetch, fresh sugar beets |
| | Fresh legume vegetables | Fresh peas with pods, peas, mange tout, broad beans, runner beans, French beans |
| | Leaves of root and tuber vegetables | Sugar beet and fodder beet tops |
| | Fresh Fungi | Champignons, canterelles |
| | Root and tuber vegetables or feed | Sugar beet and fodder beet roots, carrots, potatoes, sweet potatoes |
| 2. High acid content and high water content | Citrus fruit | Lemons, mandarins, tangerines, oranges |
| | Small fruit and berries | Strawberry, blueberry, raspberry, black currant, red currant, white currant, grapes |
| | Other | Kiwifruit, pineapple, rhubarb |

Table A4.1. Vegetable and Fruits, Cereals and Food of Animal Origin (continued)

| Commodity groups | Typical commodity categories | Typical representative commodities |
|---|---|---|
| 3. High sugar and low water content | Honey, dried fruit | Honey, raisins, dried apricots, dried plums, fruit jams |
| 4a. High oil content and very low water content | Tree nuts | Walnuts, hazelnuts |
| | Oil seeds | Oilseed rape, sunflower, cotton-seed, soybeans, peanuts, sesame, etc. |
| | Pastes of tree nuts and oil seeds | Peanut butter, tahini, hazelnut paste |
| | Oils from tree nuts, oil seeds and oily fruits | Olive oil, rapeseed oil, sunflower oil, pumpkin seed oil |
| 4b. High oil content and intermediate water content | Oily fruits and products | Olives, avocados and pastes thereof |
| 5. High starch and/or protein content and low water and fat content | Dry legume vegetables/pulses | Field bean, dried broad bean, dried haricot bean (yellow, white/navy, brown, speckled), lentils |
| | Cereal grain and products thereof | Wheat, rye, barley and oat grain; maize, rice, whole meal bread, white bread, crackers, breakfast cereals, pasta |
| 6. "Difficult or unique commodities" | | Hops, cocoa beans and products thereof, Coffee, tea, spices |
| 7. Meat (muscle) and Seafood | Red muscle | Beef, pork, lamb, game, horse |
| | White muscle | Chicken, duck, turkey |
| | Offal | Liver, kidney |
| | Fish | Cod, haddock, salmon, trout |
| | Crustaceans | Shrimp, scallop, crab |
| 8. Milk and milk products | Milk | Cow, goat and buffalo milk |
| | Cheese | Cow and goat cheese |
| | Dairy products | Yogurt, cream |
| 9. Eggs | Eggs | Chicken, duck, quail, and goose eggs |
| 10. Fat from food of animal origin | Fat from meat | Kidney fat, lard |
| | Milk fat | Butter |
| | Fish oil | Cod liver oil |

## B. AOAC Food Matrix Triangle

The AOAC Food Matrix Triangle (Figure A4.1) can be used to categorize foods and food matrix reference materials into nine sectors based on relative fat, protein and carbohydrate content [9, 19, 20]. This tool can be useful in the validation of methods intended for a wide variety of food matrices and to help in categorizing similar food matrices for methods intended for more limited applicability.

**Figure A4.1. Foods Partitioned into Sectors Based on Their Protein, Fat, and Carbohydrate Content**